EXHIBIT G

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:Master File No. :2:12-MD-0237 : :MDL No. 2327
THIS DOCUMENT RELATES TO THE CASES LISTED BELOW	:JOSEPH R. GOODWIN :U.S. DISTRICT JUDGE
Mullins, et al. V. Ethicon, Inc., et al.	2:12-cv-02952
Sprout, et al. V. Ethicon, Inc., et al.	2:12-cv-07924
Iquinto v. Ethicon, Inc., et al.	2:12-cv-09765
Daniel, et al. V. Ethicon, Inc., et al.	2:13-cv-02565
Dillon, et al. V. Ethicon, Inc., et al.	2:13-cv-02919
Webb, et al. V. Ethicon, Inc., et al.	2:13-cv-04517
Martinez v. Ethicon, Inc., et al.	2:13-cv-04730
McIntyre, et al. V. Ethicon, Inc., et al.	2:13-cv-07283
Oxley v. Ethicon, Inc., et al.	2:13-cv-10150
Atkins, et al. V. Ethicon, Inc., et al.	2:13-cv-11022
Garcia v. Ethicon, Inc., et al.	2:13-cv-14355
Lowe v. Ethicon, Inc., et al.	2:13-cv-14718
Dameron, et al. V. Ethicon, Inc., et al.	2:13-cv-14799
Vanbuskirk, et al. V. Ethicon, Inc., et al.	2:13-cv-16183

SEPTEMBER 26, 2015
DANIEL STEVEN ELLIOTT, M.D.

CAPTION CONTINUED:
Mullens, et al. V. Ethicon, Inc., et al. 2:13-cv-16564
Shears, et al. V. Ethicon, Inc., et al. 2:13-cv-17012
Javins, et al. V. Ethicon, Inc., et al. 2:13-cv-18479
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Bennett, et al., V. Ethicon, Inc., et al. 2:14-cv-29624

DEPOSITION OF DANIEL STEVEN ELLIOTT, M.D., produced, sworn and examined on behalf of the Defendants, pursuant to Notice and Agreement, on Saturday, the 26th day of September, 2015, between the hours of 9:41 a.m. and 5:54 p.m. of that day, at the law offices of Wagstaff & Cartmell, LLP, 4740 Grand Avenue, in the City of Kansas City, in the County of Jackson, and the State of Missouri, before me, NAOLA C. VAUGHN, CCR No. 1052, CRR, RPR, a Certified Court Reporter, within and for the States of Missouri and Kansas.

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(Exhibit 1 marked.)

DANIEL STEVEN ELLIOTT, M.D., a witness, being first duly sworn, testified as follows:

EXAMINATION

BY MR. SNELL:

Q. Good morning, Dr. Elliott?

A. Good morning.

Q. Can you state your full name for the record, please.

A. Daniel Steven Elliott, S-t-e-v-e-n.

Q. You and I know each other. I'll just forewarn you. I'm developing a cold and my voice is a little deep and cracky. And I have some water and I'll try to drink so it my speech is not impeded, but if you don't understand something I say today, please tell me and I'll try to pose a question that makes coherent sense to you.

Is that okay?

A. That is perfectly fine. Thank you.

Q. All right. I've given you Exhibit 1, which is the notice for your deposition.

Have you seen that document before?

A. Yes.

Q. All right. And what, if anything, did

you do to comply with the request that you bring documents and materials that is attached to that request?

A. I provided up-to-date -- well, you have already a copy of my CV. I have -- which I can provide to you. There are five new things. Just as far as what has been published, which I can provide to you there. That's a -- and then that is a copy of the manuscript, that number 5, because that just came out yesterday. So I didn't have that typed up.

Q. Did you bring your file here today?

A. The file? I'm sorry.

Q. I guess, did you bring your expert file here today that would contain the documents and materials that you reviewed and are relying on?

MR. CARTMELL: We can just -- for the record, we can get a thumb drive of everything that's on his reliance list, including that update. I just need to talk to Kuntz about that. I don't have the thumb drive with me today.

Q. BY MR. SNELL: Do you have the thumb drive, Doctor?

A. No. I don't have that, no. I have my

report. I do not have a copy of my reliance list.

Q. Okay. So we'll mark as Exhibit 2 the five new studies that would go on your CV; is that correct?

A. Correct. Those are my published studies, yes.

(Exhibit 2 marked.)

Q. BY MR. SNELL: We'll mark as Exhibit 3 article number 5, which the lead author is Linder, L-i-n-d-e-r, then Chow, then Elliott. Long-term quality of life outcomes and retreatment rates after robotic sacrocolpopexy.

(Exhibit 3 marked.)

Q. BY MR. SNELL: To what professional societies do you currently belong to?

A. That would be in my CV. Let me see if I have a copy of my CV. I might not. Oh, I do have one.

Professional societies are going to be listed in the professional membership society on page 3 of 25. AMA, American Medical Association. American Association of Clinical Urologists. American Urologic Association. International Incontinent Society. Society of Urodynamics and Female Urology, which I am a member and on the

education committee. Minnesota Medical Society. Zumbro Valley Medical Society. Olmsted Community Medical Society. International Urogynecologic Society. Society of Urologic Prosthetic Surgeons. Society of Laparoendoscopic Surgeons. Minimally Invasive Robotic Association. Minnesota Urologic Society. European Association of Urology, which I am a member of, an international member, and then I'm also a member of the subsection of Genitourinary Reconstructive Surgeons, and also a member of the section of the Female Urology and Functional Urology. And again that's underneath the umbrella of the European Urology Association. International Urogynecologic Association. International Pelvic Pain Society.

Q. In your role on the education committee for SUFU -- and that's the society of what?

A. Good question. They changed the name. Society of Urodynamics and Female Urology is an acceptable -- but, again, they've actually moved around the words a bit there, but that's what it means.

Q. Can I just call it SUFU?

A. SUFU.

Q. Make it easier on the court reporter, too.

A. SUFU is much better. I prefer that.

Q. SUFU in all caps. Okay. What is your role -- strike that.

What do you do in your role as being on the education committee for SUFU?

A. It is a -- focusing on the education not only of the current residents of what we feel would be appropriate for training in female urology, urinary incontinence and prolapse, but also determining goals, objectives of education at meetings and lecture topics, things like that.

Q. You've given testimony in the past; correct?

A. Correct.

Q. I've deposed you in the past; correct?

A. Twice, I believe, yes.

Q. So we can rely on your prior testimony. We don't have to ask you those questions again; correct?

A. Well, with the understanding that sometimes things have changed, but, yeah, as far as data being out, those types of things.

Q. Okay.

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A. That's a broad question, because those are depositions over two or three days -- or two days, excuse me. So I'd have to see each specific question what you're talking about.
Q. Okay. As you sit here today, is there any testimony that you gave in the Bellew or Gross cases that was inaccurate or untruthful?
A. No. They would all been truthful and accurate, but as the -- as data becomes available, more research being done, as I read more internal documents, certain positions may change. But there's nothing dishonest or deceitful.
Q. In connection with the education committee for SUFU, you testified that one of the things that you were involved in was looking at the training that residents would need in urology, female urology?
A. Looking at the goals or where we want residents to be, what criteria or surgeries, volumes, types of surgeries, testing, credentialing.
Q. Okay.
A. All those issues.
Q. And for the EAU, can I call that the European Association of Urology?

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A. EAU's easy, yeah.
Q. Okay. And you said you were a member of the genitourinary section?
A. Yeah. The genitourinary reconstructive. So it's reconstructive surgeons, because my training is in female pelvic medicine and reconstructive surgery, which are separate and overlapping training.
Q. That would include the surgical treatment of stress urinary incontinence?
A. That would be the other committee. That would be the female urology and functional urology. Reconstructive would be complications, radiation damage, those types of things. Anytime you hear of reconstructive, think of fixing mistakes or problems.
Q. Are you a member of the section that assesses surgical treatment options for stress urinary incontinence for the EAU?
A. Well, the members of the female functional -- we're not necessarily -- unlike the SUFU, which is an education section, this is more like the research that's being done. It's not setting goals or guidelines by any means. I don't know if that answers your questions or not.

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Q. Not really.
So just remind me, what section of the EAU is focused on assessing the surgical options for stress urinary incontinence?
A. That would be a function of the female and functional urology.
Q. Are you a member of that section?
A. Correct. And I'm on the board of that, yes.
Q. How long have you been on the board of that section that assesses the surgical treatment of stress incontinence?
A. Since April of 2013.
Q. Okay. What are your fees for your work as an expert in this matter?
A. $700 an hour.
Q. And what is your fees for testimony?
A. Same. $700 an hour for everything.
Q. Plus travel expenses and costs?
A. Correct.
Q. How many hours have you worked on the Mullins case.
And when I say Mullins, this is the MDL design defect case.
A. As far as specifically on patient

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Mullins, I have not reviewed her records. As far as TVT and design, I guess I don't know specifically -- specifically on the TVT and design, it's going to be somewhat difficult to ascertain exact time, because obviously the study of Prolift factors in.
But as far as I can determine, roughly 60 hours have been spent as of August 31st, 2015. 60 hours.
Q. How many hours have you spent since September 1st on this matter?
A. It's going to be difficult, because there's also travel involved in there. So I don't know if you want the total hours, because that's not also study on things. But that'd be about 110 hours.
Q. Do you bill $700 an hour when you travel?
A. Correct.
Q. Do you issue invoices for your time spent on this matter?
A. Correct.
Q. Do you send those to Ben Anderson?
A. Correct.
Q. And would those invoices be specific

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to and reference your work in the Mullins' TVT design defect case?
A. It will be specific to Ethicon.
Q. Okay.
A. So that's why it's difficult to determine exact number of hours, and that data reviewed two years ago is pertinent to now. So that's why it's difficult to know the total number.
Q. You're serving as an expert against other mesh manufacturers?
A. Yes. Mentor ObTape.
Q. Any others?
A. There was start in the Cook Surgisis mesh, but last I've heard there's no action going on with that.
I have been deposed with Avaulta. But, again, nothing has happened with that in six months, and I don't know where the status of those are.
Q. Avaulta, is that a Bard product?
A. Correct.
Q. That's a prolapse product?
A. Prolapse product; correct.
Q. Okay. Does the Mayo Clinic know that

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you're serving as an expert for plaintiffs in the mesh litigation?
A. No. This is all done by private time.
Q. I know I deposed you in two prolapse cases in the past. So today I'm really focused on stress urinary incontinence; all right?
A. Correct.
Q. With that said, though, let me just ask you this question.
In the Bellew deposition you testified about treatment options you used for prolapse.
Do you recall that, in general?
A. Correct.
Q. Have those changed as we sit here today?
A. No.
Q. For Exhibit 3, the robotic sacrocolpopexy cohort that you published on --
A. Yes.
Q. -- am I correct that you're not the one who runs and operates the robot?
A. No. Dr. Chow does that.
Q. Okay. Are you credentialed at Mayo Clinic to run the robot for sacrocolpopexy procedures?

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A. The answer to that probably would be no. I could be involved in the cases, but I am not the one sitting behind the robot. I am the one involved directing traffic as far as the dissection goes.
Q. Okay. What surgical options do you currently use for the treatment of stress urinary incontinence in your patients, if any?
A. Autologous pubovaginal sling, cadaveric pubovaginal sling, autologous obturator vagina sling, and then in the past since August of 2013, there's been one mesh sling. So that is a change from previous testimony.
Q. How many autologous transobturator slings do you use on average each year?
A. Probably it's around 80 or so. That's a rough -- that's a rough number. It varies from time to time. But in the past two years or -- yeah, two years now, I'd say 80 a year's probably accurate.
Q. And that's the autologous transobturator sling?
A. Correct.
Q. I know you published a feasibility cohort study on very small sample size for the

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autologous transobturator pubovaginal sling; correct?
A. Correct.
Q. That was ten patients; correct?
A. I believe so. It was ten patients, yes.
Q. There's a 20 percent failure rate at a mean average of four months' follow-up; correct?
A. Yeah. That data is now -- we're looking at 60 patients with one year.
Q. Has that data been published?
A. That's in the process of being gathered right now. All patients are being contacted.
Q. How many patients are going to be in that cohort, you said?
A. 60. It's a continuation of feasibility study. Looking at safety, efficacy, complications, et cetera.
Q. Has that data been presented anywhere in abstract form or oral presentation?
A. Yes. I'd have to go back to the CV. It was presented in February of 2015 at SUFU. Again, that was the initial feasibility study.
Q. I think my question maybe wasn't

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clear.
So on this updated cohort of 60 patients --
A. Oh, I see.
Q. -- have you presented on those data anywhere?
A. No. Not in the updated, no.
Q. And then the small feasibility study that you did publish on, you recall the mean follow-up time was to four months?
A. It was short-term, yes.
Q. What's a feasibility study?
A. Feasibility is a small cohort of patients that understand that they're involved in a study to determine whether or not this is a good treatment option, where we're doing quality of life assessments prior to and afterwards and following very closely, looking at complications and efficacy with 24-hour PAD tests.
Q. How many cadaver slings do you use on average each year? And if that's changed year to year, you can tell me that.
A. Yeah. The numbers are so -- quite variable. So it's difficult to give you a number I would say autologous slings are probably going

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to be around, let's say, 30 or so. And then cadavers are probably going to be probably less than that. Probably 10 or so a year.
Q. You do about 30 or so autologous pubovaginal slings; correct?
A. About 30 a year, yes. And that will vary dramatically, yes.
Q. And that's the traditional pubovaginal sling procedure that's been referenced in the literature for decades?
A. Yes. With the understanding that the term "pubovaginal" is not necessarily a specific way of doing it, but in general, you are correct.
Q. And that's the sling that's -- where the tissue is harvested from the patient herself; correct?
A. Correct.
Q. Okay. And the autologous pubovaginal sling is not a medical device; is it?
A. Correct. It is not.
Q. Why do you only use 10 or so cadaveric slings a year?
A. It's going to be dependent upon the patients, the specific patient, the criteria they have, multiple different surgeries, the quality of

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their tissue. Because mostly what I'm seeing in my practice is somebody that's been operated on multiple times. I'm not seeing usually the first-time patient. So, again, there's multiple patient variables.
Q. Do you have patients for whom you offer the autologous pubovaginal sling and who decline that operation?
A. I suppose that could occur, but usually those individuals are declining surgery period, not declining the autologous sling. So we have to be very careful how we're phrasing that. They are not a surgical candidate or they're choosing not to undergo surgery for their treatment. They're not saying, I do not want a autologous sling.
Q. Are there patients for whom you've treated that do not want a cadaveric sling?
A. I have not encountered that, no.
Q. Is the autologous transobturator sling the primary -- sounds like it's the primary stress urinary incontinence surgery you're doing?
A. Primary being the most common?
Q. Yes, sir.
A. That would be correct, sir, at this

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point. But, again, we're going to analyze the data.
Q. And the autologous transobturator sling is not a medical device; is that correct?
A. That's correct.
Q. The cadaveric sling is not a medical device; correct?
A. Well, it's -- it's a device -- it's a product that is purchased from the company Coloplast. So I don't think it qualifies. It's not a man-made device.
Q. It's harvested from a dead person; correct?
A. Correct.
Q. And the one mesh sling you used, I think you said in August of 2013?
A. Correct.
Q. What type of mesh sling was that?
A. That was a Coloplast product, the Supris.
Q. Why did you only use that Coloplast Supris on one occasion?
A. That was -- I can't recall the exact patient issues with that one. There was some reason why we did not -- and that's one -- it

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wasn't in August of 2013. It's since August of 2013 there's only been one. So it's a major shift in my practice. And I don't recall the reasons why we chose it, but there was a medically necessary reason, in my opinion, to do it.

Q. What type of material is the Coloplast material made of?

A. It is a polypropylene mesh.

Q. And what route is the Coloplast Supris sling placed?

A. It's a suprapubic approach. Transvaginal suprapubic.

Q. Can you explain that to me? I'm familiar with retropubic and transobturator.

A. Well, retropubic, all that means is behind the pubic bone. So it doesn't describe to a surgeon -- it doesn't describe -- it just describes an anatomical location. The TVT is bottom up. Supris or Sparc is top-down. That's probably -- that's the easier way to --

Q. So the Colopress -- strike that.

The Coloplast Supris polypropylene mesh sling uses a top-to-bottom approach?

A. Correct.

Q. And just so I'm clear, you've used

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that sling on one occasion only?

A. No. No. I've used that once since August of 2013. Prior to that, I probably placed 1200 or so. For a while there I was doing 100 to 150 slings a year. Those were synthetic slings. Those were the Coloplast, and that started in 2004 or so. So whatever the math is on that. So prior to that I used another product. So what I'm saying is I've stopped using polypropylene as a first line treatment.

Q. So from 2004 up to around the midpoint of 2013, August 2013 --

A. Correct.

Q. -- you used Coloplast polypropylene mesh slings as your primary surgical option for the treatment of stress urinary incontinence?

A. That's correct. At some point in time -- I cannot recall the exact dates -- I changed from using the AMS product, because of the problems I was having with it, to the Coloplast product. Again, we have to take with a grain of salt, it was 2004, 2005, in that time frame. And then it was exclusively the Coloplast product. No other product. No other polypropylene mesh was used.

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Q. In the past 10 years, have you used the Birch colposuspension?

A. No, I have not.

Q. In the past 10 years, have you used the Marshall-Marchetti-Krantz colposuspension procedure?

A. No, I have not. I have not personally. I've been involved in cases -- I should take that back or strike it whatever your legal terminology is.

I have been involved with GYN cases who have done the Burch. I was not the surgeon doing the Burch. I was doing something else. But I have not personally done the Burch or the MMK since fellowship, which was in '99 to 2000.

Q. How many Burch procedures have you personally done in your career?

A. Probably two.

Q. How many MMK procedures have you personally done in your career?

A. Zero.

Q. The Burch colposuspension is not a medical device; correct?

A. Correct.

Q. Besides the Supris Coloplast sling,

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what other Coloplast slings did you use?

A. The Aris. A-i -- excuse me, A-r-i-s. That is the transobturator. Same mesh, just a different route.

Q. So I take it you would have began using the Coloplast Supris before the Coloplast Aris sling?

A. I don't recall the sequence of how they were introduced. So it would have been about the same time, because in that time frame, transobturator route was available and suprapubic route, or top-down was available. I would think I probably started using both at the same time, if they were available. I don't recall exactly.

Q. Okay. You mentioned you had some problems with AMS slings.

A. Correct.

Q. Were those AMS polypropylene slings?

A. Correct. The Sparc, S-p-a-r-c, and the Monarc, M-o-n-a-r-c. Because of those problems, I stopped using the product.

Q. Sparc is a retropubic sling?

A. Correct. Top-down.

Q. Top-down. And Monarc, as I understand it, is an outside and transobturator sling?

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A. Correct.
Q. How many AMS slings do you think you placed in your career made of polypropylene?
A. Yeah. I initially started -- I'll answer your question. This is complicated. I initially started using the ObTape, which was a transobturator Mentor product. Had a horrible amount of complications.
So around in 2004 -- excuse me, 2003 -- again, I don't recall the exact dates -- I changed over to the AMS product. And so I probably placed in a period of a year or two until the Coloplast product became available -- so you have to understand this is a guesstimate -- 100 to 150 a year. So we can say 2 to 300, maybe.
Q. Okay. So am I correct that the ObTape was the first synthetic sling you placed for the surgical treatment of stress urinary incontinence?
A. Okay. We're going back 13, 14, 15 years now. That was a transobturator route. So I was doing suprapubic prior to that. I was the first in the state of Minnesota and possibly the first in the United States to use the ObTape. At least that's what the company told me. So I was actually using the Sparc prior to that. And,

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again, I know it's going to be difficult. I'm not trying to be difficult. I just can't recall the exact -- so I was definitively using suprapubic prior to that time. And then transobturator came out. The Mentor at the time had the patent, two transobturators. They were the first ones to do it. So I would have used a suprapubic route first. Then transobturator with Mentor. Had problems. Then swapped over to the AMS Monarc would probably be the sequence of things.
Q. What kind of problems did you have with the ObTape sling?
A. You name it. It was a terrible device. It was problems of buttock abscess. Extrusion rate. Pussing out. Pain. I did it in 110 patients, and we had 9 come back within a year or so with obturator fossa abscess, buttock abscess, extrusion. And then I had one patient come back in 2013. So what's that? Eight years after I implanted it with another extrusion.
Q. So you had a total of 10 patients who came back with some type of complication out of 110 for the ObTape?
A. Correct. That I know of.
Q. What type of problems did you have

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with the AMS Sparc and Monarc problems? Strike that. That was a bad question. I need water.
When do you recall first using the ObTape?
A. I'd be able to search my records and give you a pretty close to accurate date, but it would have been about in 2003, about in October or so.
Q. You did a fellowship; right?
A. Correct.
Q. What surgeries did you learn to do to treat stress urinary incontinence during your fellowship?
A. Well, that's where we did a Burch. So I'd never done Burch in residency. We only did one or two.
Q. Okay.
A. Where I was the surgeon or under the leadership of a staff.
I had already done autologous slings. So I improved my skills. I wouldn't say I was learning something new.
And then the cadaveric sling I learned there.
Q. Okay.

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A. Or first did there. I knew about it, but had first performed the procedure.
Q. In your residency, what stress urinary incontinence surgeries did you learn about?
A. Only pubovaginal, autologous pubovaginal sling.
Q. Is it correct that in your fellowship you did not learn -- strike that.
Is it correct in your fellowship you did not perform any synthetic slings to treat stress urinary incontinence?
A. That is correct. At that point in time, only the TVT was available. My staff and residency and then my fellowship staff both did not feel it was safe; so did not do it. So my first synthetic came afterwards when the Sparc came out.
Q. Is the retropubic mid-urethral sling taught in Mayo Clinic in residencies?
A. It is not taught in the urology department. I cannot speak for the urogynecology department.
Q. Is the retropubic mid-urethral polypropylene sling taught in fellowship at Mayo Clinic?

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A. Well, that would just be in the urogynecology department. We do not have a fellowship. So I don't know what they learn there.

Q. So circling back around to the AMS sling problems that you had, what were those with the Sparc and the Monarc?

A. We'd have to divide it up into each one, if you want. Kind of a -- because suprapubic approach, the Sparc, had different complications than the transobturator route.

Q. Okay. Let's go with Sparc first, and thanks for that clarification.

A. Sparc --

Q. Let me just get a good question. That was a bad question on the record.

Can you tell me the problems you saw with the AMS Sparc device?

A. Yeah. With the Sparc, it was the top-down route. We had the problem with about a 10 percent bladder perforation rate. And then also we had the problem the connector of the trochar to the mesh was bulky.

So per our routine, after we would place our trochar we would perform a cystoscopic

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exam, and we were discovering, after we had attached the mesh and pull it through, we're tearing the bladder. So we developed these bad tears in the bladder, when we would unequivocally confirmed there was no bladder hole there to start off with. So that was an unacceptable complication right there.

And then we were having a problem as far as mesh extrusion and pain. Now, that's the Sparc complications.

Q. What rate of mesh extrusion did you have with the Sparc device?

A. It was around -- that's going to be very difficult to say, because it's looking back so far now.

Q. Let me withdraw and ask you a question that I think is easier to answer, a least it may lead me to where I may want to go.

Did you or anyone else ever publish on these problems with the AMS Sparc device?

A. We never published. We spoke about -- I spoke about it. But I never had any publications on it.

Q. When you say you spoke about it, what do you mean by that?

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A. I'm going to have to clarify that statement. Actually, that's incorrect, because on my CV that I turned in, we have written up the largest series of bladder outlet obstruction requiring urethrolysis. So in that series would be some of those Sparcs that were obstructed. So I don't -- I can't give you an exact number. So that has been published on, yes.

Q. Okay. What was the rate of bladder outlet obstruction with the Sparc device in your hands?

A. I don't recall me personally having one. The other -- my colleague had a few, about a 1 to 5 percent rate of obstruction.

Q. Who is your colleague?

A. Dr. Deborah Lightner.

Q. And what was your rate of mesh extrusion with the Sparc?

A. I can just, off the top of my head, remember a few. I did not keep accurate records of the exact number of those.

Q. What was the rate of pain with the Sparc?

A. When we closely -- you know, when we asked patients to see them back, there was

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probably about a 5 percent risk, roughly, of suprapubic pain or vaginal discomfort with it.

Q. It would be routine to have the patients come back following stress incontinence surgery with a mid-urethral sling?

A. Yes or no. It depends if we're doing a study looking at something specifically. So we do not have a standard protocol to follow-up with them.

Q. So when you put in a trans -- strike that.

When you put in a Sparc sling in a patient, am I correct you did not have a specific follow-up plan for the patient?

A. We had a -- based upon efficacy only at that point in time. I remember, this is back in 2002 or 2003. We were -- and if the patients were happy, they were continent, then we did not have a scheduled follow-up for them.

Q. For the autologous pubovaginal sling that you would perform around that time, did you have scheduled follow-ups for your patients?

A. During that time frame I performed very few, almost down to zero a year. There may be an occasional one for a complicated

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reconstruction. So for a period of, what, seven, eight years my numbers of autologous slings was negligible.

Q. The Aris sling is the one made by Coloplast, which is a transobturator approach; correct?

A. Correct.

Q. When you began using the Coloplast Supris sling, how many randomized control trials, if any, were there on that device?

A. I don't recall.

Q. As you sit here today, do you know if there are any randomized control trials on the Coloplast Supris device?

A. I don't recall.

Q. Do you know or do you -- you say you don't recall. Do you know?

A. I don't know. I have not searched the literature if there is or isn't.

Q. When you began using the Coloplast Aris transobturator sling, were there any randomized control trials that existed at that time?

A. Again, I don't recall back then, no.

Q. As you sit here the today, do you know

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if there are any randomized control trials on the Aris Coloplast sling?

A. I don't know. I don't recall if there are or are not.

Q. When you began using the AMS Sparc polypropylene sling, were there any randomized control trials that existed on that device at the time?

A. I would have to theorize there were not because it was a brand-new product on the market.

Q. When you began using the AMS Monarc device, were there any randomized control trials on that device?

A. Same answer as before. I don't recall if there were or were not.

Q. Did you began doing the AMS Monarc transobturator sling when it was introduced to the market or did you wait some time?

A. No. As I recall, I used the Mentor ObTape first for transobturator route. Again, as I was told by the company, I was the first in the state of Minnesota and possibly first in the United States to do transobturator because it was brand-new. So that answers a lot of questions.

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There was no data. I recall trusting the company that there had been data, but there apparently was not.

Same answer for the Sparc that I believe that was already on the market when I began using it.

Q. But my question was for the Monarc. When you began using the AMS Monarc transobturator device, did you begin using it when it was introduced to the market or sometime later?

A. It most likely would have been sometime later. Again, I don't recall the exact dates.

Q. When you began using the AMS Sparc device, did you sit down and do a literature search to ascertain what literature, if any, existed on that device before using it?

A. The product was brand-new to the market. So there was no independent research on it and definitely no long-term studies on it.

Q. When you began using either the Coloplast sling products, the Supris or the Aris devices, did you sit down and do a literature search to assess what information and data were available on those products, if any, before using

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those products?

A. I don't recall what I did at that point in time, but there definitely were no long-term studies because it was new to the market.

Q. Now, when you began doing the AMS Monarc procedure, did you do a literature search to see if there was any data on that particular device before using it in women?

A. Again, same answer as -- there was no long-term studies. I don't recall if I did any literature searches on it or not. I was provided literature by the company, but, again, there was no long-term studies.

Q. What literature were you provided by the company on the AMS Monarc sling?

A. Their IFU and then their product publicity statement, so to speak, that has the blurbs on the product and how it's to be used and things like that, with, you know, criteria, those type things.

Q. Did AMS give you any published clinical studies or abstracts of clinical studies at the time they gave you the IFU or the publicity statement for the Monarc device?

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A. I cannot recall exactly what happened. The -- it is part of the routine of most of these reps to provide you with papers. And I don't recall that specifically with this one, no.
Q. What was your mesh exposure rate, if anything, with the Coloplast Supris device?
A. That I am aware of, I've had two.
Q. How many mesh exposures did you have with the Coloplast Aris device?
A. Oh, I'm sorry. I misspoke. Of all the -- of all the Coloplast products combined, I know of two that I've had so far. I don't know which one was which, though.
Q. Okay. So it would be fair to say for the Coloplast stress incontinence polypropylene mid-urethral slings you used, those being the Supris and the Aris, you're aware of two mesh exposures?
A. Correct.
Q. Okay. When was the last time you used a polypropylene mid-urethral sling to treat stress urinary incontinence that utilized a top-down approach?
A. That would have been the one that I did between August of 2013 to the present, and it

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would have been -- I can't recall exactly. It may have been in 2013 or early 2014.
Q. Have you ever placed a mid-urethral sling utilizing a retropubic approach from the bottom to the top like is employed with the TVT retropubic device?
A. Never. I've seen it. But I have not performed it myself.
Q. Okay. As between the -- so just so I'm clear. You've done transobturator mid-urethral polypropylene slings, and you've used suprapubic top to bottom polypropylene slings to treat stress urinary incontinence in your career?
A. Correct.
Q. What problems did you have with the AMS Monarc device, the transobturator device?
A. Similar problems as with the suprapubic, the Sparc, in that the adaptor was very large. So as you pulled it through the obturator foramen, you had to pull very hard, tug on it, stretching the mesh, and then it'd come through forcefully. So obturator pain, patient discomfort with it. We had dyspareunia. And then you had some vaginal extrusions. I do not recall -- not that it didn't happen, I do not

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recall ever seeing one of my patients who was obstructed afterwards.
Q. Okay. What was your rate of obturator pain you saw with the Monarc device?
A. Initially was essentially 100 percent. Markedly more than the ObTape. The ObTape when you placed it, the patient initially did not complain of any obturator foramen pain. The Monarc, they complained of it significantly immediately postop. We had to give a lot more analgesic, keep patients in the hospital, those types of things. So it was unacceptable problem with the device from my perspective.
Q. What was the rate of obturator pain in your Monarc patients at six months or greater?
A. I don't recall. And I don't know if we ever looked at that.
Q. What was the rate of dyspareunia in your Monarc patients?
A. Same answer as before. I don't recall. We never did a formal study on that. So I don't know.
Q. Why did you have -- strike that.
Did you find that the rate of the abscesses in your use of ObTape was unacceptable?

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A. Absolutely unacceptable.
Q. Why did you have an unacceptable rate of abscesses in the ObTape?
A. That was with the design of the product. It was a heavy weight, essentially zero pore mesh, polypropylene mesh that transmitted infection through the obturator foramen to the buttock region.
Q. For your Coloplast polypropylene slings, what type of efficacy did you see?
A. Well, there's -- again, there's the suprapubic and the obturator route. We did never -- we never looked at our rate. So I can't tell you that. Though efficacy overall was acceptable.
Q. With the AMS Sparc and Monarc devices, was your efficacy with those devices acceptable?
A. Yes.
Q. With the Coloplast polypropylene slings, did tissue integration occur with those devices?
MR. SNELL: Object to form.
A. The only way to know if there was tissue integration is to do a revision surgery on them. So we never did that.

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Q. BY MR. SNELL: Did any of your patients with the Coloplast slings made of polypropylene placed at the mid-urethral come back to you with their slings falling out?
A. Well, yeah, we had two that I mentioned that I know of came out. So you could say those two had poor integration, but I cannot speak to the others, because we did not have a routine follow-up scheduled for them.
Q. For the two patients I thought you told me they had mesh exposures.
A. They did. So that's poor tissue integration.
Q. What size were those exposures?
A. I don't recall. They're probably around the range of a centimeter or so. It was not just a mild exposure. These required treatment.
Q. And was the tissue integrated in the area beyond the mesh exposure in those two cases?
A. Again, I can't recall going back that far. I know it was not at the location of the extrusion, though.
Q. What was the pore size of the Coloplast polypropylene mesh?

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A. I don't know.
Q. Was the Coloplast polypropylene mid-urethral sling mesh that you used mechanical cut or laser cut?
A. It's actually different. It's hemmed. So the border of it looks completely different than the TVT or the Sparc. So you don't have the roping, the fraying particle loss with it or elongation. That's why I liked it over the Sparc procedure.
Q. Did the Coloplast IFU for their sling products you used provide the frequency, severity, and duration of complications?
A. I don't recall what the IFU said.
Q. Did you read it?
A. Yes, I read it.
Q. As you sit here today, do you know whether those IFUs on the Coloplast mid-urethral slings ever reported frequency, severity, or duration of complications?
MR. CARTMELL: Objection. Asked and answered. He just said he didn't recall.
A. I don't recall, sir. It's been a long time. I know I'm required to review it, but I don't recall what they stated.

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Q. BY MR. SNELL: What was the weight of the Coloplast slings you used for stress urinary incontinence treatment?
A. 70 grams per meter squared.
Q. For the AMS Sparc and Monarc slings, what was the pore size of those products?
A. Well, it depends if it's coming out of the box or once you've implanted it. And so the answer is, I don't know because it was quite variable. When you placed it in the patient and then pulled on the trochars, pulled the sheath around it, it would elongate and pull and roll up. And so you'd get this rope look appearance to it, which the pore size was zero, essentially -- excuse me, not zero. It was negligible.
Q. How many Sparc and Monarc slings did you place in your career?
A. And that's in a period of probably two, maybe three years, a rate of 100 to 150 a year.
Q. And when did you first see this roping and elongation of the Sparc and Monarc slings?
A. As soon as we started putting it in.
Q. So you began -- just so I understand, as soon as you began seeing -- strike that.

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As soon as you began using the AMS polypropylene mid-urethral sling, you began seeing the roping and elongation?
A. Correct.
Q. Yet you continued to place 100 to 150 of those a year?
A. That is correct, because I didn't know the significance of it at the time.
Q. Is the Sparc polypropylene sling mechanical cut or laser cut?
A. I believe it is mechanical cut. In appearance it is identical to the TVT.
Q. Does it have blue striping as well?
A. Has a blue thread through it. Prolene -- or I believe it's Prolene suture. I'm not sure. And that was placed there not initially. That was placed afterwards to prevent the problem of it rolling, because when you'd tension it, it'd roll up.
Q. And for the Monarc sling, is that mechanically cut or laser cut?
A. Same answer as the Sparc. It appears to be mechanical cut. I can't speak for the cut. I've not reviewed those documents, but it appears to be mechanical cut.

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Q. Did you ever see particles falling off of that mesh?
A. When you would pull on it, either the Monarc or the Sparc, they're the same mesh, you would pull and then you would get these little tiny fibers, like just little things that you could actually see on your glove. And so the answer to that question is yes.
Q. And that did not deter you from using those products?
A. I was unaware of the significance at the time.
Q. Well, you knew you were implanting polypropylene into the body; right?
A. Correct.
Q. And those little particles you would see on your glove were made of what?
A. Polypropylene.
Q. Does the Monarc have the blue striping as well?
A. Yeah. It has a blue Prolene -- well, I assume Prolene -- suture going through end to end. That's for tensioning purposes. That was added later.
Q. Have you ever looked at the MSDS

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sheets that pertain to the Sparc or Monarc products?
A. No, I have not.
Q. Have you ever looked at the MSDS sheets that pertain to the Coloplast sling products?
A. I have not.
Q. Why not?
A. Because I don't know how to find them.
Q. Am I correct; you never used the TVT retropubic device?
A. Correct. Correct. You're right.
Q. And when I say TVT retropubic, I mean the original, still-on-the-market-today Ethicon manufactured TVT retropubic device.
A. Correct. The bottom up. They also have a top-down. But bottom line, I have not used any Ethicon product for stress urinary incontinence.
Q. Okay. So that makes it fast. Great.
Before writing your report in this case, did you review the order issued by the judge regarding the design defect claim in Mullins, and what the judge expected the parties to focus on in this matter?

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A. I don't --
MR. CARTMELL: Let me object to the form.
MR. SNELL: Okay.
MR. CARTMELL: I'm not sure what you're talking about, frankly, and I'm not sure he will either. So it may call for speculation.
A. I've reviewed a lot of documents, some coming from Judge Goodwin. I don't recall the nomenclature you're using.
Q. BY MR. SNELL: Okay. Have you seen any orders by Judge Goodwin in the Mullins case?
A. Again, same answer as before. I don't -- I've seen a lot of stuff coming from Judge Goodwin with his signature or whatever on it. I just don't recall the nomenclature you're talking about.
Q. I looked through your report, and your footnotes begin on page 11; correct?
A. That is correct.
Q. Actually, if you turn to page 9, you have a footnote at the top, but there's no citation to it.
A. Yeah. That is correct. That's a typographical error, it looks, appears.

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Q. Okay.
A. That's my comment. Yeah, there's no reason to reference that.
Q. Okay.
A. That's my comment.
Q. Okay. So looking at your report, beginning on page 11 where you have Footnotes, the majority of what you cite -- that way we can just see if we can agree to this.
In your expert report -- strike that.
The majority of things that you cite in your expert report in footnotes are either Ethicon company documents, testimony by company witnesses, or papers concerning hernia mesh or prolapse.
Is that a fair statement?
MR. CARTMELL: Object to the form.
A. Well, the majority -- you're correct. There's internal documentation. Many depositions. There's the significant amount of medical literature in the canine model, rabbit model, human, and then there's TVT references in there, too. So I can't say that -- there's a lot of different references from a lot of different sources.

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Q. BY MR. SNELL: Well, for the medical literature, it's correct, isn't it, that you cited to a lot more hernia literature than you did TVT literature?
A. That is --
MR. SNELL: Object to the form.
A. That is correct, because TVT is a hernia mesh.
Q. BY MR. SNELL: And if we go to the back of your report, on page 32, you cite to the recent Cochrane Review by Ford, et al.?
A. Page 32? I'm sorry.
Q. Yes. Footnote 97, I see.
A. That is correct.
Q. What is a Cochrane Review?
A. Cochrane Review -- well, I actually have a copy of it here. A Cochrane Review -- I can give you the exact nomenclature that they use. Yes. The Cochrane database, which is a -- I believe it's government sponsored, that is in charge of analyzing studies and a combination of studies to hopefully be able to come up with analysts -- analysis of papers and their efficacy, their quality, et cetera.
(Exhibit 4 marked.)

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Q. BY MR. SNELL: I've handed you Exhibit 4. This is the intervention review of mid-urethral sling operations for stress urinary incontinence in women by Dr. Ford and others; correct?
A. Well, this is the abbreviated form of it, the summary.
Q. Right.
A. The real document is -- I don't know how many pages, but is a very big document.
Q. Right.
A. But, yes, this is the summary, as you have stated.
Q. And this is the same Cochrane Review you cited; correct?
A. Correct. One by Ford, et al., in 2015.
Q. And it looks like -- the publication status and date, this actually -- Cochrane Review was published this summer; correct?
A. July. Correct.
Q. And if you look in the abstract -- let me ask you this: Why did you cite to the Cochrane Review?
A. Multiple different reasons. It's a

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large study. It's one of the bits of evidence. I try to look at all evidence out there, whether it be pro or con for mesh so I can get a balanced opinion on this. And this is one of the documents. And it's an updated one. 2015.
Q. Okay. Under the background, they state that the mid-urethral sling operations are a recognized minimally invasive surgical treatment for stress urinary incontinence.
You see that?
A. That's what they state, yes.
Q. You would agree that the mid-urethral sling is minimally invasive compared to the autologous pubovaginal sling which requires harvesting of tissue from the woman?
MR. CARTMELL: Object to the form.
A. I would agree, minimally invasive is always a statement, has to be with qualifiers or a comparison to. And I think it would be ligament to say the mid-urethral sling is less invasive than the autologous sling.
Q. BY MR. SNELL: Would you agree that the mid-urethral sling, particularly the TVT retropubic is less invasive than the Burch colposuspension?

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MR. CARTMELL: Same objection.
A. You know, possibly. But, again, depends how you do it. Some people can do it with a very small incision, and it's -- but it depends upon -- again, it's very difficult because you have to pass those trochars blind. So that's an invasive thing. It's a stab wound to a patient. What's the difference in making an incision and putting your stitches in. But you could say, yes, it is going to be less -- the TVT is going to be less invasive somewhat than the Burch.
Q. BY MR. SNELL: Would you agree that the TVT retropubic device is less invasive than doing an MMK?
A. I think, again, same as the Burch answer. The MMK requires more lateral dissection. So I think that's a fair statement.
Q. The MMK, as I understand it, has about a 2.4 percent risk of the osteopubitis. Am I saying that correctly?
A. Correct. It should not be that high of a percentage, but that is a risk of it, correct.
Q. But you've read literature summarizing that risk is 2.4 percent by authors Drews and

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others?
A. I've read literature from other people saying it is less than 1 percent. But I'm not going to deny it. Yes, there is a risk of that, and that's probably one of the reasons it's not done very much.
Q. And how did patients in the MMK -- strike that.
The MMK is a open procedure?
A. Correct. I don't recall anybody doing it laparoscopically, but it's a procedure not done very often anymore.
Q. How does osteopubis occur in open procedure like the MMK?
A. They're thinking it's irritation to the bone with the sutures.
Q. The main results of this Cochrane Review -- I want to go down a little bit.
First of all, they included 81 trials; correct? I'm on this page here, Doc.
A. Oh, I'm sorry. Yes.
Q. That evaluated 12,113 women; correct?
A. Correct.
Q. The quality of most outcomes was moderate; correct?

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A. Yes. It reads, "moderate, mainly due to bias or risk of imprecision."
Q. And the vast majority of these studies that were included in the Ford Cochrane Review that you cited are what are called randomized control trials; correct?
A. I'm sorry. I don't understand your question. Can you -- there's misspellings on that. So can you -- I'm sorry.
Q. Do you know what a randomized control trial is?
A. Yes, I do.
Q. Of course you do. What is a randomized control trial?
A. Randomized control trial would be a level 1 trial on the Oxford education levels, where there are two different groups that are equally randomized to two separate treatment arms. And then you do the same evaluations and the same pre and postop description of patients and outcomes.
Q. Okay. You mentioned the Oxford. I've heard of the Oxford Levels of Evidence.
Is that what you're referring to?
A. Yes. That's fine.

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Q. And what is the importance, if any, of Oxford Levels of Evidence?
A. It is trying to quantify or demonstrate or show individuals the data that is gathered from various different studies. It does not mean that other studies are invaluable, such as case reports. But when you're trying to compare apples to oranges or different types of apples to each other, you need to compare them directly to each other. And you get arguably the better data from that type of a study.
Q. Level 1 you said was an RCT?
A. Correct.
Q. What is level 2?
A. Level 2 is a case controlled trial. Comparisons are made, but they're not randomized.
Q. You pulled out a document. Could we mark that as Exhibit 5? Thank you. Oh, okay.
(Exhibit 5 marked.)
Q. BY MR. SNELL: I just want to look at it real quick, and then I'll give it right back to you.
So where would the Cochrane Review that you cited in your expert report rate on that level of evidence pyramid?

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A. Cochrane Review is really not on it. Cochrane Review is an analysis of all the data out there. It's like a meta-analysis. Meta-analysis which are used extensively don't fall into these categories. These are smaller studies. Cochrane or meta-analysis are a combination. Like they mentioned, 81 trials that evaluated 1200 patients. Hence the reason why there'll be weaknesses or errors within those studies because they're analyzing potentially bad studies.
Q. I've seen a similar evidence pyramid that has on top, above an individual randomized control trial, something called systematic reviews in meta-analyses.
A. Yeah. That's why I mentioned meta-analysis. I'm not familiar with that.
Q. Okay.
A. But, again, as I mentioned, meta-analysis, if you take bunches of poor quality studies, you're not going to get out of that magically a good quality study. If you take dog doo and make a lot of dog doo, you still have dog doo. So you have to be careful on those types of analyses. And that's why they mention here in this Cochrane one, the quality, at most, was

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moderate, and they indicate the reason why.
Q. Do you rely on meta-analyses?
A. I look -- I'm a reviewer for 15 different journals, and twice been awarded the best reviewer in Journal of Urology. I look at them with skepticism, because it's just -- again, as I mentioned, you have to know what goes on on each and every study to know if it's a good quality study. If you take a lot of good quality studies and put them together, that's quality. And that's why there's going to be selection, and that's why certain studies won't meet criteria. But if you just take everything and analyze it, again, it's the -- a lot of dog doo. You got a big dog doo at the end.
Q. So you are aware there's a Cochrane Review for the pubovaginal sling published by Remmen.
A. I don't recall that title. I'd like to see that one. I don't recall that one.
Q. Let me ask you this: Do you know if there's a Cochrane Review that analyzes the pubovaginal sling?
A. Yes. By Remmen.
Q. So if I mispronounce a name, you can

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answer yes and correct me. I'm okay with that.
And the quality of evidence on the pubovaginal slings by Remmen was noted to be poor; correct?
A. I don't recall. I'd have to see that. I have no reason to think -- I have no reason to think that you would be wrong with that, though. I'm going to see if I have that the study. Yeah. I don't -- without knowing how to spell it, I don't know how to find it. Okay.
Q. You would agree that overall the quality of studies on pubovaginal slings is poor?
A. I would say the overall studies on incontinence, in general, are moderate to poor. There are very few high quality studies out there.
Q. But my question is specific to the autologous pubovaginal sling. You would agree for the autologous pubovaginal sling, the quality of evidence on that procedure is poor?
A. As with all the other treatments, I would agree with you, yes.
Q. You mentioned there were a few high quality studies. What would those be?
A. For which procedure?
Q. For the autologous pubovaginal sling.

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A. There's a paper by Chaken, et al. There's another one by McGuire's group at University of Michigan, both of which had 100 percent patient involvement. Some up to -- involvement. Contact. So zero dropout rate except for a death, and up to 10 years of follow-up.
Q. Neither one of those studies are randomized control trials; correct?
A. Correct.
Q. They were both retrospective cohort studies; correct?
A. Yeah. The data was prospectively gathered, retrospectively reviewed.
Q. And they were single center studies; correct?
A. Correct.
Q. And Ed McGuire is the surgeon you're referring to out of Michigan; correct?
A. Well, he was actually down in Houston at the time that he wrote it, but he had been in Michigan.
Q. For the Burch colposuspension, are there any high quality studies that you're aware of?

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A. Yeah, there are several. I have a Langer, et al., 10 to 15 years of follow-up, Burch colposuspension, from internal -- International Urogyn Journal.
Q. Do you recall what the loss to follow-up was in the Langer Burch paper?
A. Of the 156 patients, 29 were admitted for not completing a 10-year follow-up. 8 patients died. Can't blame them for that. 21 could not be located. So actually -- so they had -- death would not factor into it. So you have 21 out of 1156 were lost to follow-up.
Q. The 29 patients, what happened with them?
A. Well, that's what I'm saying. 29 patients were not studied. 8 died.
Q. Okay.
A. And 21 could not be located. So that equals a percentage of 13 percent lost to follow-up.
Q. And one of the issues or problems with longer term studies is that patients can die, succumb to mortality, as you follow over a decade or more; right?
A. Correct.

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Q. And that's recognized in the field as an issue when looking at randomized -- strike that.

When looking at longer term studies?

A. Yes and no with that. Death is looked at differently than loss -- than a true loss to follow-up. They had the 21 patients that were not able to be located. Those are important. The 8 that died are still important. It's sad they died, but you look at that data differently. And statistically it's different. And that's a follow-up over 12.4 years, median follow-up.

And you also asked the question about other studies. There's also Herbertsson, et al., H-e-r-b-e-r-t-s-o-n, and then I'll spell the next one, K-j-o-e-h-e-d-e, which had 14-year follow-up, and those are specifically on Burch. So here's three studies with greater than 10 years of follow-up.

Q. Can I see the paper you were looking at real quick. Can we mark this, Doctor, as an exhibit?

A. Sure.

MR. SNELL: What number.

(Exhibit 6 marked.)

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Q. BY MR. SNELL: Look at table 5, Doctor.

A. I'm there.

Q. There's a 22 percent rate of detrusor instability; correct?

A. That is what they quote, yes.

Q. And what is that?

A. That -- I'd have to see how they define it. De novo detrusor instability was found in 17 patients. So that means, following the procedure, it caused de novo overactive bladder symptoms. So their overall rate they state is 29. But only 17 of those were caused by the procedure.

Q. Okay. So about two-thirds were caused by the procedure?

A. Yeah. 58 percent. So 17 out of 127 had de novo. 13 percent. So when you look at graphs and tables, that's why it's difficult to be a good reviewer. You have to look at the whole big picture. Not just one graph.

Q. All right. The rate of dyspareunia was 3.9 percent in this Burch study?

A. That is what they quote. Again, I'd have to look at the study exactly, if that's de novo or if that's preexisting or not. I'd have to search for that.

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Q. Isn't 3.9 percent rate of dyspareunia with the Burch acceptable?

A. Well, I think ideally you want a zero percent dyspareunia, but you'd have to know and which this study does not have, which I would critique if I were reviewing it, is a qualifier of how bad that dyspareunia is. Is it dryness or is it a complete inability to have intercourse due to pain, but it says 3.9 percent.

Q. Right. And my question is: Is that 3.9 percent rate of dyspareunia with the Burch in the paper review reference acceptable?

MR. CARTMELL: Object to the form.

A. Again, I need to know if it was de novo or not.

Q. BY MR. SNELL: So you can't answer my question?

A. I would, if I can find dyspareunia in here, where they discuss it. Yeah. I don't see it. We can take a long time. I can search for it. But I would need to see how they're describing it in those things.

Q. I didn't see it either.

A. That is an issue with many studies.

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It is not included. That's why we keep saying moderate quality. No. There's only -- in the document there's only one time they mention dyspareunia, and it's in that graph. So there's no qualifiers to it.

Q. But it's still a paper you pointed me to as important with regard to the Burch colposuspension; correct?

A. That is correct.

Q. Back to the Cochrane Review. We were looking at the Results section in the fourth paragraph. It says, "The overall rate of vaginal tape erosion/extrusion/exposure was low in both groups." It was 21 out of 1,000 for retropubic mid-urethral sling.

Do you see that?

A. That is what they state for the study, yes.

Q. That's 2.1 percent; correct?

A. That is -- that is what they state, yes.

Q. The 2.1 percent would be the incidents of the mesh exposure; correct?

A. Well, that's what they state with the understanding that these are short-term, moderate

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quality studies, within the hands of high-quality large volume surgeons.
Q. So these 31 trials that they assess, did all of those trials involve short-term follow-up?
A. Well, in the situation of meshes, this is an implantable permanent medical device. Anything short-term -- or short of lifelong follow-up is going to be inadequate, from my perspective. So this is going to be short-term. I doubt any of these are over 10 years, and even that, in my opinion, is inadequate. But you'd have to look at each individual study to find out what follow-up duration was.
MR. SNELL: Move to strike as nonresponsive.
Q. BY MR. SNELL: The 31 trials that were assessed, is it your testimony that all of those trials are short-term trials?
MR. CARTMELL: Object to the form.
A. I would have to see this complete document to see each of those follow-ups to see if they're adequate or not.
Q. BY MR. SNELL: Is there any lifelong follow-up data on the Burch colposuspension,

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reporting a mean follow-up of 30, 40, 50, 60 years in women?
A. Well, as you've pointed out, it's not a medical device. There doesn't need to be. There can be for efficacy, but for safety and complications, that's going to be all perioperative. So there does not need to be. You're comparing apples to oranges.
MR. SNELL: Move to strike as nonresponsive.
Q. BY MR. SNELL: For the Burch colposuspension, are there any lifelong follow-up studies?
MR. CARTMELL: Objection. Asked and answered. He just answered your question.
MR. SNELL: I don't care whether he thinks it's necessary or not. I'm asking him is it -- all right. Do those exist. That's a yes or no or he doesn't know.
MR. CARTMELL: Well, he said no and explained why it's not important.
MR. SNELL: I don't think he said no, Tom. He gave me a speech.
MR. CARTMELL: Well, you can say no, and explain again why it's not important.

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Q. BY MR. SNELL: Let me reask the question.
For the Burch colposuspension, are there any studies that have lifelong follow-up of the patients?
A. As I stated, the Burch is not a medical device. So, no, there are no long-term studies, but there don't need to be because there's no permanent implantable product in the patient.
Q. But the Burch can lead to dyspareunia, just like the paper you showed me; right?
A. No. I disagree with that. As I stated, dyspareunia was recorded, but I have no idea the preoperative incidence of dyspareunia.
Q. So it's not important to track dyspareunia with the Burch colposuspension?
A. No. You are spinning my words. That's incorrect. I stated, in that paper there's one word of dyspareunia. I don't know; did 10 percent have dyspareunia preop? They don't mention it. Hence the quality of the paper goes down.
So from your argument, the 10 percent could have been preop, now it's down 3.9. So they

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did a good job.
Q. Do you know which way it went?
A. As I stated, the paper does not mention that.
Q. Is it important to track dyspareunia with the Burch colposuspension?
MR. CARTMELL: Object to the form.
A. Dyspareunia and safety of the device is always important to track. It's going to be different for different products. If you have a permanent implantable device, you have to follow it lifelong. If you have a device that's absorbed, gone away, it's not as important to follow.
Q. BY MR. SNELL: So it's not as important to follow dyspareunia with the Burch colposuspension; is that what you're saying?
A. For as long a duration.
Q. Is it important to follow and assess dyspareunia with the Burch colposuspension out to 10 years?
A. It would be an interesting fact. However, again, there's no permanent devices placed in a woman. So I am more concerned about the shorter term, five years, those type things.

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But even that, the suture's absorbed. It's healed up. So really you can't compare TVT mesh, or any mesh for that matter, and the Burch or autologous fascia for that matter.

Q. There's scarring when you do a Burch colposuspension; correct?

A. Yes. By six weeks it's healed up.

Q. And it's not important to assess whether there's any painful scarring in a Burch?

A. Absolutely there is, but the duration of the follow-up, the perioperative morbidity is extremely important. But after you've done the surgery, and there's healing that's happened, which 98 percent happens at six weeks, one, two, five-year data is important to look at. But it's not as important because you don't have the progressive scarring, et cetera, that you see with the polypropylenes.

Q. How would one go about assessing the lifelong -- give me a second.

Can I see the exhibits. 1, 2, 3. You can hold on to this one. The Burch study we marked a minute ago.

A. Oh, I'm sorry. I took that back. There you go.

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Q. Okay. That way she has it.

A. Okay.

Q. You have 5 over there?

A. Oh, I'm sorry. I'm taking those.

Q. That's okay.

All right. You can hold on to that one. I still have some questions.

How would one go about conducting a lifelong study on the Burch colposuspension?

A. A registry would be mandatory where these individuals are followed. And you can't have a 30 or 40 or 50 percent fallout rate. And they have to be monitored on a yearly basis until death. And then the true complication rate in those highly experienced surgeons' hands would then be known.

Q. And a registry being mandatory monitored yearly until a woman's death has never been performed for the autologous pubovaginal sling; correct?

A. Again, for the same mentioned -- as the reasons I mentioned for the Burch. There's no permanent implantable device placed in that woman. So the perioperative morbidity is very important, but it has not been done for the pubovaginal

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sling, as you described.

MR. SNELL: Move to strike everything before "it has not been done."

Q. BY MR. SNELL: A registry being mandatory with monitoring yearly until the death of all women has never been performed for the Burch colposuspension; correct?

A. As I've mentioned already, because there's no permanent device implanted in the woman, it is not necessary, but to answer your question, yes.

MR. SNELL: Move to strike everything before "to answer your question, yes" as nonresponsive.

Q. BY MR. SNELL: For any stress urinary incontinence surgery that's ever been performed that you are aware of, has there ever been a registry conducted that was mandatory that monitored every woman yearly until her death?

A. Unfortunately, no. And that's why we're in the situation we're in now.

Q. Looking back at the Cochrane Review you cited in your expert report --

A. Yes, sir.

Q. -- it says in the next paragraph, "A

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retropubic bottom-to-top route was more effective than top-to-bottom route for subjective cure."

Do you see that?

A. That is what is stated, yes.

Q. And the TVT is the retropubic bottom-to-top route; correct?

A. As far as I know, that is the only bottom -- with the understanding -- let me back up.

With the understanding that from my understanding at this point right now, TVT is the only one on the market bottom-up. So I don't know if there's another one on the market.

Q. You have looked at the -- you looked at the entire Cochrane Review from 4/2015 over -- I think it's over 200 pages?

A. Very long document, yes.

Q. Right. Right. Right. And you saw that the retropubic bottom-to-top studies were studies that assessed the TVT retropubic device; correct?

A. I don't recall that. Again, I have no reason to doubt that. I'm just saying, there are a lot of companies that used to make slings, Boston Scientific, Bard, et cetera. I just don't

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know of another one. If that study says there's only one bottom-up and it's the TVT, I can't disagree with that. I just don't know right now.
Q. You certainly know that the TVT retropubic device has been studied in more randomized control trials than any other stress urinary incontinence surgical device; correct?
MR. CARTMELL: Object to the form.
A. I have -- I have heard a lot of facts like that. I have never independently verified that to be true, but I don't doubt its existence.
Q. BY MR. SNELL: It says the retropubic bottom-to-top route also "incurred significantly less voiding dysfunction and led to fewer bladder perforations and vaginal tape erosions"; correct?
A. That is what they state, yes.
Q. And those would be benefits of using a retropubic bottom-to-top route like the TVT retropubic employs as compared to a top-to-bottom route; correct?
MR. CARTMELL: Object to the form.
A. Well, correct except that Ethicon makes a TVT-AA, which is top-to-bottom. So based upon what they're saying here, TVT-AA would be included in the top-to-bottom. So this would be

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very worrisome that perhaps that TVT product employed in that fashion is actually more dangerous.
Q. BY MR. SNELL: Have you ever assessed the literature on the TVT-AA device?
A. There's limited data out there.
Q. But have you assessed it?
A. Yes, I have assessed it, and there's limited data on it.
Q. And how does the voiding rates compare between the TVT retropubic and then the top-down TVT?
A. The data overall with all sling products is very poor. With TVT-AA it's even worse. So I don't know. I cannot quote you a study looking at that, but I'm just saying the Cochrane analysis possibly raises the issue of a TVT-AA.
Q. As you sit here today, you don't know, though whether the TVT-AA was assessed in top-to-bottom in the Cochrane Review?
A. That's what I'm saying.
Q. Do you know whether the Supris was assessed in this Cochrane Review?
A. I don't know.

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Q. It wouldn't surprise you to learn that there were no randomized control trials on the Supris; correct?
A. As I stated earlier, I was unaware of any, and hence the reason why sling data is bad. Or poor quality, let's put it that way.
Q. Have you conducted an analysis of the literature regarding slings to see whether any of the other manufacturers' polypropylene slings have been subjected to more randomized control trials than the Ethicon TVT retropubic device?
A. I have not done any independent research on that.
Q. Have you done any PubMed searches to assess how many hundreds or thousands of studies there are on the TVT retropubic? And when I say TVT -- strike that.
When I say studies, I'm not limiting it just to randomized control trials.
A. I understand.
Q. I mean cohort studies, studies that would comport with the level of evidence pyramid, levels 2 and 3 that you identified.
MR. CARTMELL: Object to the form.
A. My methodology that I use when I

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approach any of these projects is going to involve multiple different facets, but one of them is using the PubMed search engine, which is -- as far as I know, the largest search engine available, funded by the NIH. And when I search just TVT, only TVT, it comes up with about 1300 papers. But that's going to be TVT-Secur, TVT-AA, TVT -- all the TVTs.
Q. BY MR. SNELL: Did you do any other search string modifiers like "tension-free vaginal tape"?
A. I don't recall that --
Q. TVT retropubic?
A. I don't -- well, TVT is going to capture all TVTs. Tension-free vaginal tape -- I don't recall if I used that, I may have. But I searched multiple different factors looking at, you know, mesh complications associated with those things.
Q. How many studies on TVT did you locate on PubMed?
A. I found roughly 1300 on all TVT products, the entire product line.
On just TVT retropubic or TVT classic, I can't give you a number.

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Q. Okay. How would the TVT retropubic have less voiding dysfunction than a top-to-bottom device like the Sparc that you used?
A. With my training in neurophysiology, neuroanatomy and bladder dysfunction, it does not make any intuitive sense why that difference would be. You're passing a trochar up -- from bottom up or top down, you should be -- there's -- the voiding dysfunction should be identical.
There's going to be variables, such as the mesh, the experience of the surgeon, the amount of tension placed on it, the patient factors in there. That's where the Cochrane analysis -- we don't know; were the patients morbidly obese; were they diabetics; their previously existing bladder dysfunction. All those factors I don't know.
Q. So I guess the answer to my question then would be, you do not know how there would be less voiding dysfunction seen with the TVT retropubic as compared to a top-to-bottom device like the Sparc; correct?
MR. CARTMELL: Object to the form. Asked and answered.
A. Well, the statement, quote/unquote, I

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don't know, implies I haven't thought about it. I've thought a lot about it. It does not -- I cannot come up, to answer your question, with a logical explanation why that's occurring. There's a variable we don't know. Is it poor quality studies? Patient variables? Those issues. As I mentioned earlier in the previous question.
Q. Okay. How is it that the TVT retropubic would have less vaginal tape erosions than a top-to-bottom route, such as the Sparc that you use?
A. Well, I do not use the Sparc and haven't used it for 10 years or so. Or less than that. Excuse me.
But, again, we have to include in there -- unless you can show me in the Cochrane study does not include the TVT-AA, that there can be some of the Ethicon product in there.
But to answer your question, it does not make logical sense, based upon the anatomical approach, to have more or less or vaginal extrusions. That's why there's going to be some of a variable in there that we don't know in these studies.
Q. What was the size of the vaginal

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incision you did when you used the Sparc?
A. Be 1 to 1.5 centimeters.
Q. And what was the other top-to-bottom device you used?
A. The Supris.
Q. Supris. What was the size of the vaginal incision you used with the Supris?
A. Same thing. 1 to 1.5 centimeters, mid-urethral.
Q. And did you do blind passage of the trochars with any of those devices?
A. Correct. With the Supris and the Sparc, that is the identical length of blind passage as with the TVT.
Q. And did you do blind passage with any of the transobturator slings you performed?
A. Yes. But it's a degree -- significant degree less, because you have your finger in the obturator foramen. So you're passing that around the obturator foramen, which is about 1 centimeter, but that would be blind.
Q. All right. You would use your finger and that's known as haptic or tactile feedback; correct?
A. I suppose. It is tactile. It's

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feedback. Yes, you're right.
Q. And that's commonly done in pelvic surgery?
A. Pelvic surgery does a lot of surgery by proprioception. Yes, by feel.
Q. And for the autologous transobturator pubovaginal sling, part of that procedure is blind; correct?
A. No. I disagree with that because when you do a different dissection, you dissect through the endopelvic fascia bilaterally. You dissect along the pubic bone up to the rectus muscle. Then you're able to palpate from your incision in the abdomen, feel right where your finger is. So you pass it through the rectus muscle and then on to your finger. So there's no blind passage of 5 to 10 centimeters like with the Sparc or the TVT.
Q. But there is a blind package in that procedure. It's just shorter; correct?
A. A significant -- well, no, there's no organs that can get away. That's why there's no bladder perforation, or extremely rare. In my experience, I've never perforated the bladder with it. Where I had a 10 percent Sparc bladder perforation. And you're passing it right onto

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your finger. So there's -- you know, we can splice and say, yes, there is some blind passage, but it's right onto your finger. So you're passing it through the rectus muscle. So you're talking a centimeter.

Q. In the autologous pubovaginal sling placement there's blind passage performed; correct?

A. I've already answered that. That's what I just stated.

Q. I'm not talking about the transobturator.

A. Oh, I'm sorry. You said transobturator?

Q. In the autologous pubovaginal sling that you do.

A. Isn't that what I just answered already?

Okay. I mean, that's the same answer as what I just stated. That your finger's right up there against the rectus muscle. The needle goes right through the rectus muscle onto your finger. So there's no blind passage, like the 5 to 10 centimeters like with the TVT or the Sparc.

Q. I may have got confused or maybe you

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didn't hear my earlier question right.

For the autologous transobturator pubovaginal sling, that was my initial set of questions.

Those involve blind passage; correct?

A. That would be the same -- actually, less than with the mesh slings because we dissect deeper right underneath the muscle. So the same answer would be for the abdomen as with this. We're passing it through the obturator foramen onto your finger. So it has no chance of getting into the bladder. So if you want to define that as blind, I'll give that to you, but it's a -- it's a safe passage. It's right on your finger. I'm sorry. I misunderstood your first question.

MR. SNELL: It's okay. Let's take a break. We've been going for a bit. I want to use the restroom, if that's okay.

MR. CARTMELL: Sure.

(Recessed from 11:22 a.m. to 11:41 a.m.)

Q. BY MR. SNELL: Back on the record.

Two of the studies you mentioned in addition to this study by Langer, L-a-n-g-e-r, were studied by Herbertsson, which is reference 8

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in the Langer paper; correct?

A. Correct.

Q. And then the Kjoehede. And I'm not sure if I'm pronouncing that correct.

Do you know if that's right?

A. Yeah. My Swedish is not very good. But that would be reference number 9.

Q. Okay.

A. Correct.

Q. And do you know what percent of the women were dry in follow-up in the Kjoehede study?

A. I do not. I'd have to look at the study.

Q. Do you know what percentage of the women were dry in follow-up of the Herbertsson study?

A. No, I'd have to look at the study.

Q. And I think that's spelled can H-e-r-b-e-r-t-s-s-o-n, published in Acta, A-c-t-a, Obstet Gynecol Scand, 1993, volume 72, pages 298 to 301.

Correct?

A. That is correct, yes.

Q. And looking back at the Cochrane Review that we were discussing, under the author's

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conclusions.

A. Yes, sir. Sorry.

Q. You have it there?

A. Yes, I do. I have both. I have my copies and then your copy.

Q. Great. For the record, can we mark your copy, too, then?

A. Sure.

Q. Just so I can look at it at some point.

(Exhibit 7 marked.)

Q. BY MR. SNELL: So Exhibit 7 is your copy of this Cochrane Review by Ford, et al. we've been discussing?

A. That is correct. This is the abstract off of PubMed.

Q. Okay. And under the author's conclusions, it says, "mid-urethral-urethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence."

You see that?

A. Yes, I do.

Q. And you will agree with that; correct?

MR. CARTMELL: Object to the form.

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A. Again, I have no reason to doubt it. But I've not done independent research on that knowledge.
Q. BY MR. SNELL: Okay. And also it says, "and have a good safety profile."
You would agree with that; correct?
MR. CARTMELL: Object to the form.
A. That statement needs to be taken in the entirety of the paragraph, where they say longer term studies are needed. But that is what they state.
Q. BY MR. SNELL: And you agree with that; correct?
MR. CARTMELL: Object to the form. You just asked him the question. And he answered it.
A. I agree that's what they state. And then it has to be looked at in the entirety of the paragraph where they say longer studies are needed.
Q. BY MR. SNELL: And my question to you is: You agree with that conclusion; correct?
MR. CARTMELL: Object to the form. Asked and answered.
A. I disagree with the conclusion because

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longer studies have not been done.
Q. BY MR. SNELL: Well, you agree that mid-urethral sling operations have a good safety profile with the caveat that you would like to see more long-term studies done; correct?
MR. CARTMELL: Object to the form. That misstates his testimony. And I'm not going to let you do this thing where you do -- you ask four different times the same question, like we did the last time.
MR. SNELL: That's fine.
MR. CARTMELL: He's asked -- don't answer that. You've answered it three times.
MR. SNELL: No, he hasn't. No, he hasn't.
MR. CARTMELL: Yes, he has.
MR. SNELL: No.
MR. CARTMELL: He answered your question. You asked if he agreed with the conclusion. He said no.
MR. SNELL: You're wrong, Tom. He said not because of the caveat that it needs more long-term study. So there's my follow-up question, Tom. You're playing games with me.
MR. CARTMELL: No, I'm not.

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MR. SNELL: Stop it. Knock it off, Tom.
MR. CARTMELL: No, I'm not.
MR. SNELL: Knock it off, Tom.
MR. CARTMELL: He answered your question no.
MR. SNELL: No.
MR. CARTMELL: And I'm not going to let you do this again. We're not going to sit in here for seven hours where you ask the same question five times because you don't like his answer.
MR. SNELL: It's not about whether I like his answer.
MR. CARTMELL: He told you he disagrees with the conclusion. So move on.
MR. SNELL: No, he didn't. You're misstating, Tom.
MR. CARTMELL: Tell him again.
MR. SNELL: You're giving speaking objections on the record.
MR. CARTMELL: We're going to do this once.
MR. SNELL: This is my question.
MR. CARTMELL: We're not going to do

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it again.
MR. SNELL: Just knock it off. This is my question. You're wasting my time. This is your time you're burning here, not mine.
Q. BY MR. SNELL: You would agree mid-urethral sling have a good safety profile with the caveat that you, Dr. Elliott, would like to see more long-term data on those procedures; correct?
MR. CARTMELL: Object to the form. It misstates his testimony. He's already answered it.
A. I disagree with that.
Q. BY MR. SNELL: Very well. Would you like to see more long-term data on the autologous pubovaginal sling?
A. Long-term studies are always going to be important. However, when we're talking about safety and complications, it's comparing apples to oranges because there is no medical device placed in those patients that's permanent.
Q. Can you answer it yes or no?
Would you like to see more long-term data on the autologous pubovaginal sling?
MR. CARTMELL: Objection.

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Q. BY MR. SNELL: A procedure that you perform.
MR. CARTMELL: Objection. Asked and answered.
A. I don't necessarily know if it is actually needed. On efficacy, I would agree with you. On safety, I disagree.
Q. BY MR. SNELL: This paper you gave me by Langer on the Burch says that more longer term studies are needed on the Burch because of safety; doesn't it?
A. I'd have to look at the study.
Q. Here. How about we look at the very last sentence. "The most significant complications are de novo detrusor instability (16.6 percent) and anatomical defects (18.9 percent), half of which appeared only 5 years postoperatively, stressing the need for long-term follow-up."
A. I never denied --
Q. Did I read that correctly?
A. I have no reason to doubt that you -- that's the editorial comment. You said the author's conclusion. So you read the editorial comment. I have it highlighted there.

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Q. That's not what I read. I read this.
A. Okay. Now, number one, you didn't show this what you were reading so I don't know what you're reading. I go down here, and they say longer term studies.
Q. I'm not reading your highlights. I'm reading what I stated.
A. Okay. That's what the author states. I'm not disagreeing with that at all.
Q. So there is long-term follow-up needed on the Burch to assess safety considerations; correct?
MR. CARTMELL: Objection. Asked and answered.
A. They never say safety. They're talking about de novo instability and anatomical defects, which anatomical defects can occur in any woman with any type of -- as long as they have a vagina there could be prolapse happening. They're not talking safety. They're talking contraction, roping, those type of things.
Q. BY MR. SNELL: They're talking safety; aren't they?
A. They're talking de novo instability. Okay. That's new afterwards. Anatomical defects,

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which can occur, but it's not an issue of safety.
Q. Those authors categorized those two issues as complications; didn't they?
A. They record them as complications; that's correct.
Q. Back to the Cochrane Review that you cite in your report. It says that "The mid-urethral sling-urethral slings are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long-term; correct?
A. That's what they state, yes.
Q. And you would agree with this paper you cited in your report that mid-urethral slings are highly effective in the short and medium term?
MR. CARTMELL: Object to the form.
A. I will never say that the -- I will not -- I agree with you as far as effectiveness. I'm never going to be challenging the effectiveness of the TVT as far as causing -- or in treating urinary incontinence. The question is always going to be at what cost.
Q. BY MR. SNELL: We can agree that the TVT retropubic device is effective in the treatment of stress urinary incontinence in women?

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MR. CARTMELL: Object to the form.
A. Correct. With the caveat, at what cost.
Q. BY MR. SNELL: All right. There is no stress urinary incontinence surgery that is performed in women that is more effective than the TVT retropubic; correct?
MR. CARTMELL: Object to the form.
A. More effective? I would have to look at all the literature out there on pubovaginal slings, including the Burch. I would say it's safe to say that the TVT, as far as efficacy, on the average, is going to be -- specifically dealing with stress urinary incontinence recurrence, is going to be as efficacious as pubovaginal and Burch, in properly trained hands.
Q. BY MR. SNELL: And you've seen a conclusion very similar to that which you stated about TVT being efficacious in the treatment of stress urinary incontinence, as compared to pubovaginal slings and the Burch in the Ogah/Cochrane Review; correct?
A. That's correct. Yeah.
Q. That's a paper --
A. They state that that -- yeah.

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Q. That's a paper you reviewed; correct?
A. Correct. Yes.
Q. You didn't cite the Ogah review in your report. Why not?
A. Because I stayed the Ford one, which is an update. So I'm not going to go back to Ogah. I'm going to go to the most updated literature.
Q. Ogah compared TVT to the Burch and pubovaginal slings, though?
A. Okay.
Q. You're aware of that; right?
A. Yeah.
Q. Any reason you didn't cite that comparative data by Cochrane?
A. Because that's going to be a Cochrane analysis of compiling a meta-analysis, so to speak.
Q. Okay.
A. So using my methodology there's going to be some papers that are not going to included and others are going to be included.
Q. You would agree that there's accruing evidence that -- demonstrating the efficacy of TVT retropubic in the long-term?

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MR. CARTMELL: Object to the form. Are you talking just efficacy?
A. Well, again, I'd have to see what you're talking about as far as which papers you're referring to. But since the product has been in a long time, naturally there's going to be longer -- or hopefully there's going to be longer term studies.
Q. BY MR. SNELL: You're aware there are several studies that have a duration of follow-up of seven years or more with the TVT retropubic device?
A. Correct.
Q. I'm not talking about other manufacturers' devices.
A. Yes. There are studies out there, yes.
Q. Due to your -- let me back up.
I don't know if I asked you this question. If I did, I apologize.
You and I can agree that with regard to long-term studies following up on a mid-urethral sling that the original TVT retropubic has the most long-term data of any of those devices?

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A. You'd have to show me that study.
Q. Well, it's not just one study. I'm just saying from your general awareness, are you aware that for the original TVT retropubic device it has the largest volume of longer term data compared to other manufacturers' stress incontinence mid-urethral sling devices?
A. I think that's probably a fair statement, yes.
Q. Have you assessed the literature to ascertain how many studies with 10 years follow-up or more exist on the TVT retropubic device?
A. Have I -- I'm sorry. I'm not really following your question.
Have I assessed how many 10-year studies there are?
Q. 10-year or more. Yes, sir.
A. I looked at the literature. I reviewed it. There are studies out there. I can't give you a number, though.
Q. Are you aware if studies that look at 10 years duration or more specific to the TVT retropubic device assess safety issues, such as mesh exposure or dyspareunia?
A. I am unaware of any study that the

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primary end point is on safety with the TVT. There can be a paper here and there with large amounts of follow-up -- with large amounts of lost follow-up that can refer to an erosion or exposure.
Q. So you are aware that in the longer term studies with TVT they do assess safety?
A. You'd have to show me those studies. I'm sorry. Because I have to look at those studies very carefully. As I mentioned, I am not aware of any with the primary end point being on safety.
Q. I didn't ask you about primary end point. I asked you about assessing safety, okay?
Are you aware of TVT retropubic device studies looking at it long-term that assess safety?
MR. CARTMELL: Object to the form. It's vague and ambiguous as to what you mean by assess.
A. There can be random --
Q. BY MR. SNELL: They look on and report about whether there were mesh erosions, mesh exposures, dyspareunia, detrusor instability.
Are you aware of that?

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A. They can mention -- there are studies out there that mention those various different facts. They also, you know, very rarely talk about contraction because it's not -- those patients aren't examine. They're telephone follow-ups. So, again, I'd have to look at those specific studies and we can analyze that. I'm all for that. But otherwise you're talking somewhat vague for me.

Q. What studies, long-term studies on TVT are you referencing where patients were not assessed?

A. Well, no. I'm saying that we'd have to pull out a study and look at it, how many of those patients came back and had a physical exam. How many of them did quality of life surveys. How many of them did global bother index. And those studies are very few. Hence, the reason why all these different societies, the AUA, for example, keep talking about moderate to low quality of studies.

MR. SNELL: Move to strike as nonresponsive.

Q. BY MR. SNELL: Admit your primary end point on safety.

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How many Burch or pubovaginal sling studies are you aware of that have long-term follow-up that have a primary end point of safety?

A. And you -- with -- oh, Burch or pubovaginal.

I'm aware of pubovaginal because that's the procedure I'm doing. So I'm going to be more focused on that. That have 8 to 10-year follow-up where global bother index and distress inventories have been obtained.

Q. Right. But how many of those had a primary end point of safety?

A. It was part of the study. It was not the primary end point.

Q. Just like the TVT studies; right? It was part of the study?

MR. CARTMELL: Object to the form.

A. Incorrect. As I've mentioned before, pubovaginal slings and Burch are not a permanent medical device that's implanted in a woman. Therefore, the bar is changed for the pubovaginal and Burch, okay.

But to answer your question, I am aware -- I am not aware of any primary end point on safety with those other ones. But, again,

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we're comparing apples to oranges.

MR. SNELL: Move to strike everything before "But to answer your question."

Q. BY MR. SNELL: On the Cochrane Review that you cite in your report, the last page they say, referencing mid-urethral sling operations, are suitable for women who have -- who are having their first operation to prevent incontinence and also women who have had unsuccessful surgery previously.

A. I'm sorry. I don't know where you are.

Q. Back --

A. You're in the Author's conclusions?

Q. Background information.

A. Oh, Background.

Q. It's the next page, if you flip it over. Are you with me now?

A. Yeah. Which paragraph are you on on Background?

Q. Second paragraph.

A. Second paragraph starting with, "Over the years"?

Q. Second sentence.

A. It starts, "Over the years"?

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Q. Yes.

A. And second sentence, "These operations are suitable for women...."

Okay. Yes, I see that statement. Yes.

Q. Would you agree that the TVT retropubic device is suitable for women who are having their first operation to prevent incontinence?

A. I disagree strongly with that unless the caveat is that the woman and the physician have been fully warned of all the complications known.

Q. A little bit further down, we were talking about long-term studies. And they talk about the main findings of this review.

A. Under Author's conclusions?

Q. Right here. We were here.

A. Yeah.

Q. So Main findings.

A. Yes, sir.

Q. So under the Main findings of the review, they stated that the trial showed over 80 percent of women with stress urinary incontinence are cured or have significant

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improvement in their symptoms with either operation for up to five years after surgery.
A. Yes, I see that statement.
Q. Is that an accurate statement?
A. That is the findings of their studies.
Q. Do you --
A. And I have never -- and as you look at my expert report, ever challenged TVT's efficacy. That's not an issue with me. It's at what cost.
Q. At the end of that paragraph it says, "The evidence that we have been able to assess indicates that the positive effects persist."
Do you see that?
A. Yes, I see it.
Q. You did not challenge that statement either; correct?
MR. CARTMELL: Object to the form.
A. The evidence that they're saying is they're talking about the durability of the treatment for stress urinary incontinence. As I mentioned, I'm not challenging that. The question is at what cost.
Q. BY MR. SNELL: Yeah. We can agree TVT retropubic -- that that device has durability for treating stress urinary incontinence in women?

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A. Yes, I believe that the data, in my clinical experience, would agree with that statement.
Q. And that is a utility of the TVT retropubic device; correct?
MR. CARTMELL: Object to the form. It's vague and ambiguous with respect to what you mean by "utility."
A. The device is designed specifically to treat female stress urinary incontinence.
Q. BY MR. SNELL: Okay.
A. And so to answer your question then, it has durable results in the long-term, but the question is at what cost.
Q. Okay. The TVT retropubic device is useful in treating female stress urinary incontinence; correct?
MR. CARTMELL: Object to the form. It's vague and ambiguous with respect to what you mean by "useful."
A. It has been shown to be efficacious. The question is at what cost.
Q. BY MR. SNELL: In this study -- strike that.
In this Cochrane Review you cite, they

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also talk about main findings pertaining to adverse effects; correct?
A. Correct.
Q. And it says, "Tapes passing behind the pubic bone (retropubic) seem to carry a greater risk of injuring the bladder"; correct?
A. Oh, that is correct.
Q. All right. And that's been reported in the literature; correct?
A. Yes. And that's pertaining to either bottom-up, top-down.
Q. But even for the TVT retropubic, going bottom-up, it's been known that there's a risk of hitting the bladder with the trochars. That's why a cystoscopy is done; correct?
A. That is correct. And the big question then becomes the ramifications of that perforation, long-term erosions and those things -- erosions and extrusions, yes.
Q. When you did your top-down passage with the mid-urethral sling, I take it you also did cystoscopies as well?
A. Always, yes.
Q. I know the AUA recommends cystoscopies for all incontinence procedures, surgeries, as I

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understand it.
Is that consistent with your understanding, based upon their updated stress incontinence guidelines published by Dmochowski, et al.?
A. Dmochowski. Yeah. I don't even know how to spell his name, but I know how to say it. It's no problem.
I'd have to look at the specific guidelines. For retropubic procedures, whether they're top-up, bottom-down, mandatory cystoscopy.
Transobturator tends to be -- they say they suggest it's strongly supported, but it can be at the discretion of the treating physician.
Q. Do you do any cystoscopy when you do any transobturator procedures?
A. I do not, no.
Q. You don't?
A. No.
Q. Why is that?
A. Because in having done 400, 500 or more of those, I've never once hit the bladder, because I'm dissecting right onto my finger, and I bring it right out. I don't use the helical trochar. Now, I've seen and taken care of a lot

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of patients with it, but I've never caused it.
Q. Okay. A little further down in that paragraph in the Cochrane Review, under Adverse effects, it says, "There is moderate quality evidence that overall reported rates of tape-related complications are low, such as erosion of the tape into the vagina at about 2 percent for both routes of tape insertion."
Did I read that correctly?
A. Yes, you did.
Q. And do you agree with that?
A. Disagree.
Q. I didn't see in your expert report where you identify what the rate of mesh exposure was with the TVT device.
A. That's because the true rate is not known.
Q. I didn't see where you reported any rates of mesh exposure based on any studies for the TVT retropubic device.
MR. CARTMELL: Is that a question or statement?
Q. BY MR. SNELL: Am I correct, Doctor?
MR. CARTMELL: We'll stipulate that that's not in there.

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A. I don't believe and I don't recall stating a specific number, no.
Q. BY MR. SNELL: And this Cochrane Review you cite to in your report does say that "The reported occurrence of problems with sexual intercourse including pain was low"; correct?
A. That's what they state, yes.
Q. And you didn't acknowledge that point in your report; did you?
A. I talk about dyspareunia in there.
Q. Did you acknowledge that the Cochrane Review that you cite to states that problems with sexual intercourse, including pain, were low in your report?
A. I don't recall using those specific words, no.
Q. Why not?
A. Because, again, this is a meta-analysis of poor quality or moderate quality studies that do not focus on dyspareunia. And specifically they're short-term studies. It does not tell -- also, these are in the hands of experts, high-volume surgeons. Does not tell us the rate of the true average surgeon out there, which is known to be much higher.

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Q. You say these studies are done by expert high-volume surgeons.
First of all, how do you define an expert high-volume surgeon?
A. Well, Kuuva, et al., defined it as anybody doing -- they said the learning curve on the TVT is 15 or greater.
Okay. So any -- most surgeons in the United States, based upon people sitting for the oral boards for urology, are doing 1 to 2 slings a year. Those people are not experts, but those are the people putting in the majority of slings.
Okay. Now, to answer your question, how do we define an expert, it's going to be tough to say, but they're going to be doing more than that number.
Q. Do you have a definition or a number in your mind, when you keep mentioning expert high-volume surgeons, what that is to you?
A. It also -- because there's not a specific answer to that because it depends upon their level of training coming into the procedure or did they do a fellowship. Did they learn from an expert. Did they have Ulmsten or Nilsson come in and teach them how to do it. Those numbers are

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going to be different than an average person who goes and has a three-hour Ethicon meeting and then goes back out in the middle of nowhere USA and puts them in. For me, I would have to say if they're not doing at least 25 or greater slings -- specific sling a year, they are going to possibly be putting that patient at risk for complications.
Q. Well, this study -- strike that.
This Cochrane Review included 81 trials. So of all the investigators in all of those 81 trials, how many of them performed at least 25 or more TVT slings in a given year?
MR. CARTMELL: Do you want him to look at the underlying data and tell you that?
MR. SNELL: I want him to answer my question, Tom.
MR. CARTMELL: Well, but you know --
A. Let's get the Cochrane analysis out and I'll look at that.
MR. CARTMELL: Yeah.
Q. BY MR. SNELL: Well, did you bring it here?
A. No, I don't have that.
Q BY MR. SNELL: So you can't answer my question?

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A. Well, no, but you brought up the issue. And so you have a question that I can't answer based upon -- we have two pieces of paper, 81 studies. That should be roughly, what, 150 pages of data. I'd have to go through and look at that.
Q. So as you sit here today, you can't answer that?
A. I just answered -- I just already answered that because you have not provided me with the information I need.
Q. I asked that you bring your file to this deposition. You didn't bring it.
A. Because with this study --
MR. CARTMELL: Wait. For the record. Let me just say this. You have been provided his reliance list that has every single document on it he reviewed and relied on. It has this document that you only -- the full document. You only provided a summary document. So if you wanted to ask him questions about the full document, you knew he reviewed it and relied on it. You could have brought it.
MR. SNELL: Here's why, Tom, I'd like him to bring his file. The document he did

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produce has notes on every single page of the studies. So whatever I could pull off the internet or elsewhere, will not be the version that he has that has his notes on it.
MR. CARTMELL: Okay. Now, he didn't have to provide you that today. He brought it with him today. I mean all you -- the rules say that we got to give you is the reliance list and the materials. And I've told you, I'll give you the materials on a -- what do you call it?
MR. SNELL: Thumb drive.
MR. CARTMELL: Thumb drive. But you have it all. You have it all.
MR. SNELL: I would like those with his notes on them. Not your version of them. I want Dr. Elliott's file.
MR. CARTMELL: He gave you a study that has his notes on it. I don't know what he has that has notes on it or not, okay? But the bottom line is you have the reliance materials and you know every single study and paper and internal document he's relied on.
MR. SNELL: I don't think I know that.
MR. CARTMELL: Yes, you do.
MR. SNELL: All right. So move on.

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(Exhibit 8 marked.)
Q BY MR. SNELL: So, Doctor, I've handed you the American Urological Association's position statement on the use of vaginal mesh for the surgical treatment of stress urinary incontinence from October 2013.
You're aware of this; correct?
A. Yes.
Q. And this is the same association you're a member of; correct?
A. Yes.
Q. And the AUA says suburethral synthetic polypropylene mesh sling placement is the most common surgery currently performed for stress urinary incontinence"; correct?
A. Yes.
Q. Do you know whether that statement is accurate or not?
A. I don't know if it's accurate or not. I have no reason to doubt its validity, though.
Q. I think you're familiar with the paper by Chughtai, et al., that reports on the different types of stress urinary incontinence surgeries performed by urologists certifying or recertifying for their boards that found the mid-urethral sling

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to be the dominantly used procedure?
A. I recall the name of that study. I don't recall the data. But, again, I have no reason to doubt that it's the most common. But I have not done independent research to verify that.
Q. Okay. The AUA statement says, "Extensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female SUI."
A. That's what they state, yes.
Q. And that's an accurate statement; correct?
MR. CARTMELL: Object to the form.
A. No. That's what they state.
Q BY MR. SNELL: I know that's what they state, but that is an accurate statement; correct?
MR. CARTMELL: Well, is that a statement by you, or are you asking him if he agrees that's accurate?
Q. BY MR. SNELL: I'm asking you if you agree that's accurate. What I just read to you.
MR. CARTMELL: Object to the form. He just answered that question.
MR. SNELL: He said that's what they say. I know that.

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A. The document, as it says now, Extensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of SUI."

As we've stated before, it is effective, along with pubovaginal slings and Burch, to treat SUI. So I agree with that.

Q BY MR. SNELL: Okay.

A. Minimal morbidity compared to the alternatives, I disagree with. So I guess, I can't --

Q. Okay.

A. It's a complicated or -- not a compound sentence, whatever the -- multiple aspects of t the sentence.

Q. What Cochrane reviews or meta-analyses or randomized control trials report that the TVT retropubic has -- strike that.

When you say you disagree that the mid-urethral sling have minimal morbidity compared with alternative surgeries, why do you say that?

A. Because there have been very few randomized control trials, none which are long-term, comparing head-to-head autologous pubovaginal slings versus TVT. The only one I can

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think of off the top of my head is Amaro, et al., from International Journal of Urology, I believe.

Q. Do you agree that with regard to the TVT retropubic as compared to the pubovaginal sling and the Burch that it has an advantage, including shorter operative time?

A. It is shorter. Whether that's an advantage or not -- surgeons get too caught up in doing something in, say, 15 minutes. So it is shorter. I'll give that to you.

Q. Okay.

A. Is it an advantage? That's debatable.

Q. Okay. Is it an advantage of the TVT retropubic device that it can be done, if chosen, locally, as compared to the Burch and the pubovaginal slings?

A. Well, that's a difficult question. Is that an advantage? I suppose in some highly select patients. In all my years of doing this at a high-volume tertiary center, I've never once had to do a procedure under a local, as far as a sling. I mean, so that's a theoretical potential advantage.

Q. I'm not even going to ask you about Burch.

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When you do the autologous pubovaginal slings, you do general anesthesia?

A. That is correct. Or spinal.

Q. Or spinal. And that's because that's a painful procedure when you have to harvest that tissue from the lady; correct?

A. No. You don't want them moving during the procedure.

Q. It wouldn't be painful if that was under local anesthesia?

A. You could do it under local. It's been done under local.

Q. Is the autologous pubovaginal sling commonly done under local anesthesia?

A. No, I would say it is not, no.

Q. Why not?

A. Just as I mentioned, patient's going to be moving. And you'd have to inject local underneath the rectus fascia. It could be done. But for patient comfort, most patients don't want to be awake for it. You just don't do it that way.

Q. So when the AUA says, "Advantages include, and they say anesthetic need, what do they mean by that?

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MR. CARTMELL: Object to the form.

A. I suspect they're probably meaning postop analgesia.

Q BY MR. SNELL: Is that a benefit of the TVT retropubic compared to Burch and pubovaginal sling?

A. Well, the statement they say "Advantages include shorter operative time and anesthetic need."

Q. Um-hum.

A. Somewhat ambiguous. I don't know if they mean intraop or postop. But if you're looking just at the short-term, just at the time of the perioperative period, that would theoretically be an advantage. But, again, it's at what cost long-term.

Q. When you say perioperative period, what are you referring to?

A. Meaning right before surgery, meaning 10 minutes before surgery, the surgery, and then immediately postoperative. Like the first few weeks.

Q. They also say, "Another advantage would reduce surgical pain."

Do you agree that TVT retropubic has

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reduced surgical pain, and that that is an advantage?
A. Well, but, again, we have to go back to the lack of studies. Again, I'm always aware of Amaro, et al., TVT randomized versus pubovaginal. In that study, hospital duration was the same. And so that is debatable. But, again, let's look at the short-term. I got to look at long-term. As a surgeon, I got to look at long-term, 10 years on down the road. So I can give that to you with the caveats I mentioned.
Q. So in the short-term you'd agree TVT retropubic has the potential for reduced surgical pain versus the Burch or the autologous pubovaginal sling?
MR. CARTMELL: Object to the form.
A. I agree, in the immediate postoperative period, let's say within the first -- define that as the first six weeks of surgery --
Q BY MR. SNELL: Okay.
A. -- especially the first week, I think it's acceptable to say that the TVT would have less perioperative pain than the Burch or the pubovaginal sling.

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Q. When you do your pubovaginal slings, do you give your patients pain medicines?
A. Yes.
Q. Why?
A. To reduce the perioperative pain.
Q. How long do you give them pain medications?
A. We give them 10 to 15 tablets of a narcotic, and they take it if they need it. They stop it if they don't. So I don't know how long they take it.
Q. Do you agree that and advantage of the TVT retropubic device is reduced hospitalization?
A. Disagree.
Q. Why is that?
A. Based upon Amaro, et al., that hospital duration was the same for the TVT and the autologous pubovaginal sling.
Q. Do you know of other TVT versus autologous pubovaginal sling randomized control trials?
A. As I sit here right now, I'm not aware. I'd have to go back and look at the literature.
Q. In general, not isolated to a single

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RCT. So for the practice of stress urinary incontinence surgery in the United States, over the time period TVT retropubic device has been available, would you agree that there is reduced hospitalization with it compared to the autologous pubovaginal sling and the Burch?
A. I think there's going to be data out there that supports it's a faster, quicker, and less hospital stay on the average. But, again, we have to look at the randomized control studies. But, again, that's not an issue I'm debating. It's the long-term risks that I'm talking about.
Q. It says another advantage is reduced voiding dysfunction.
Do you believe that's a potential advantage for the TVT retropubic versus the autologous pubovaginal slings?
MR. CARTMELL: Object to the form. It's vague and ambiguous with respect to what you mean by voiding dysfunction.
A. Well, no, I disagree with that. I'd have to say show me the -- that one very specifically, you're going to need level 1 data to support that. You cannot take cohort studies and compare cohort to cohort. And so that one is

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highly debatable.
Q BY MR. SNELL: When you see "voiding dysfunction" -- and this is written by the organization that you belong to; right?
A. Oh, yeah, and I know the people who wrote it. One's on staff with me.
Q. When you see the term "voiding dysfunction" -- Mr. Cartmell objected as vague.
What did the AUA mean by "voiding dysfunction" in this position statement.
MR. CARTMELL: Object to the form.
A. Yeah, when these guys and women get together, this is a big argument, because, again, I know the people on this board and I'm at the meetings. I don't go -- I'm not a member of this and the guidelines.
But voiding dysfunction can be anything. Stress incontinence, overactive bladder, urgency frequency, nocturnal enuresis, bladder pain with urination. Voiding dysfunction is very vague. And hence, the reason why Rovner, et al., wrote up a follow-up article in this in the AUA newsletter.
Q BY MR. SNELL: Actually, Rovner's follow-up was before this was reissued. You know

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that; right?
A. This was were the --
Q. October 2013.
A. 2013 is the one I'm referring to.
Q. This paper was issued after Rovner's commentary?
A. Well, no, this is a revision of the original; wasn't it? I'd have to look at when the first one came out, and it's a revision of it. Update.
Q. On the very back page, October 2013, revised. Correct?
A. Yeah.
Q. They state that "mesh-related complications can occur following polypropylene sling placement, but the rate of these complications is acceptably low."
Do you see that?
A. Yes, I do.
Q. "It is the AUA's opinion that any restriction on the use of synthetic polypropylene mesh suburethral slings would be a disservice to women who choose surgical correction of SUI."
Do you see that?
A. Yes, I do.

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Q. "Multiple case series and randomized control trials attest to the efficacy of synthetic polypropylene mesh slings at 5 to 10 years."
Do you see that?
A. Yes, I do.
Q. "The efficacy is equivalent or superior to other surgical techniques." Correct?
A. That's what it states, yes.
Q. And you've seen literature and data that supports that statement?
A. As it pertains to efficacy, I agree. I mean, equivalent, I think is fine. And superior is debatable, and you have to look at those specific studies, but I'm not going to argue that.
Q. "There is no significant increase in adverse events observed over this period of follow-up"; correct?
A. Yeah. And that's the actual key right there, "over this period of follow-up," which is short-term.
Q. How do you define -- did I ask you how you define "short-term"? I know you've mentioned that term.
A. Yeah.
Q. Can you define "short-term" for me as

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you have used it?
A. It's going to depend upon the procedure we are discussing, but when specifically in TVT, from my perspective, based upon the literature and what's out there, as far as degradation, et cetera, anything short of lifelong is going to be insufficient.
MR. SNELL: I don't think -- move to strike as nonresponsive.
Q BY MR. SNELL: I'm trying to get a definition from you. So when you use the term "short-term," what do you mean by that?
A. Short-term specifically relative to polypropylene meshes --
Q. Okay.
A. -- because it is a permanent implantable device, shown to have degradation in Klinge, et al., up to 15 years, Ethicon's statement showing that degradation continues, contraction, et cetera. Anything less than lifelong, to me, is short-term and insufficient.
Q. And you like to apply a different bar to the Burch colposuspension; correct?
A. Burch and also the autologous because -- specifically because those are no

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permanent implantable device. With that said, for example, when the ProteGen sling was used in the past, the Gortex sling was used in the past, then I would say for those, you need to have lifelong follow-up.
Okay. But, again, when we're talking about autologous tissue, the patient's own, or Burch, where there's no tissue used, the products -- there's no product in there to have lifelong problems with.
Q. So how do you define short-term as to the autologous and the Burch?
A. Well, a minimum study criteria established about four, five years ago, said any study less than 12 months for sling procedures was insufficient.
So, again, it depends on what you're looking at in a study. But if we're looking at efficacy, efficacy is a different story. Efficacy can be lifelong. But if we're looking at perioperative complications, then really two years out. Patients heal. But there is no written in stone what short-term, long-term is.
Q. I was just following up, though, because you used those terms, and I want to know

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what it means to you.
So what is short-term --
A. Short-term --
Q. -- in the context of an autologous pubovaginal sling?
MR. CARTMELL: Are you talking about in the context of a study?
MR. SNELL: Not a particular study. He says short-term.
Q. BY MR. SNELL: I want to know what you mean by that.
A. I understand.
Q. You've told me about the TVT and stuff, and I hear you. But now I want to know what standard do you apply to the Burch when you say short-term?
A. Less than 12 months.
Q. Okay.
A. Less than 12 months. Arguably, 24 months.
Q. And what do you mean -- strike that.
What standard do you use for the definition of short-term with regard to the autologous pubovaginal sling?
A. Same thing. 12 months definitively.

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Arguably 24 months.
Q. Okay. Is that for safety, too?
A. Yes. But, again, we don't have any permanent implantable device with those other procedures. So perioperative morbidity is a more important issue.
Q. Well, you know there can be permanent sutures placed at the time of the autologous pubovaginal sling or a Burch; correct?
A. Yes. And those are --
Q. And you know there can be suture or --
MR. CARTMELL: Let him finish. Hold on? Yes, and those are?
A. Yes, and those are usually Prolene sutures, which we've been told by Ethicon are safe. However, in my practice, I've had two patients develop suture granulomas; so I don't use them. I use Vicryl sutures.
Q BY MR. SNELL: And you know that suture erosion can occur with those -- any type of permanent suture; correct?
A. Then that raises the very real possibility of those sutures causing degradation, inflammatory reaction, foreign body response, which we know happens in the dog model. That's

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been discussed. Ethicon knows that. So that actually is a very good point. Perhaps Prolene is not safe product, as we've been told.
MR. SNELL: Move to strike as non-responsive.
Q. BY MR. SNELL: My question was: It's known that permanent sutures can degrade. In fact, it's known that permanent sutures can have suture erosion if employed with the Burch colposuspension or the autologous pubovaginal sling procedure; right?
A. Incorrect.
Q. You haven't seen publications by people like Ed McGuire and others that report suture erosions following an autologous pubovaginal sling at an average duration follow-up of greater than 24 months?
A. If you're doing a pubovaginal sling in the classic way where it's described, where the Prolene sutures are high up in the abdomen, away from the bladder, there should be zero erosions. If somebody's doing a variant of it, that's a different story. I can't speak to that. Burch is the same thing. You have a Prolene suture, which we know degrades based upon studies, okay, which

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are outlined in my expert report. Ethicon knows it. Prolene, as a much suture, degrades. If you knot it up and put it by the bladder, you can have degradation, foreign body reaction, and then subsequently erosion. So, yes, the question is why.
MR. SNELL: Move to strike as nonresponsive.
Q. BY MR. SNELL: My question was: Do you know there are studies that report suture erosions by people who do the autologous pubovaginal sling, like Ed McGuire, that report suture erosions at a follow-up of greater than 24 months?
A. I would have to see that exact study and we'd have to review it, see how they did the study. But, again, it raises the issue of why that's occurring.
Q. My question is: Do you know whether or not the data exists?
A. I answered that and said I'd have to see the studies you're talking about and how they did the procedure.
MR. CARTMELL: Lunch is ready when you are.

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MR. SNELL: Is it. Yeah, let's go ahead and do lunch.
(Recessed from 12:30 p.m. to 1:01 p.m.)
(Exhibit 9 marked.)
Q BY MR. SNELL: Doctor, I've handed you the Position Statement on mid-urethral sling-Urethral Slings for Stress Urinary Incontinence By IUGA.
You're familiar with this document?
A. Yes, I am.
Q. This is one of those professional societies to which you belong today?
A. That is correct.
Q. And similar to the AUA statement that we looked at, it talks about efficacy of the mid-urethral slings; correct?
A. Correct.
Q. And it talks about safety of mid-urethral slings; correct?
A. Yeah. It discusses it, yes.
Q. All right. In the third paragraph, when they're talking about mid-urethral slings, they state that "They have been shown to be as effective as more invasive traditional surgery

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with major advantages of shorter operating and admission times and a quicker return to normal activities together with lower rates of complications."
Do you see that?
A. Yes, I do.
Q. Do you disagree with the IUGA position statement?
A. I disagree.
Q. "This has resulted in the mid-urethral sling becoming the operation of choice in Europe, Asia, South America, South Africa, Australasia," A-u-s-t-r-a-l-a-s-i-a, "and North America for the treatment of SUI with several million procedures performed worldwide."
Do you see that?
A. Yes, I do.
Q. Do you agree or disagree with that statement that it is the operation of choice as amongst the alternative surgeries?
A. It is the most common procedure --
Q. Okay.
A. -- I mean, performed.
Q. A little further down it says, "There is robust evidence to support the use of

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mid-urethral slings from over 2,000 publications making this treatment the most extensively reviewed and evaluated procedure for female stress urinary incontinence now in use."
Do you agree with that?
A. I have not looked at that.
Q. "These scientific publications studied all types of patients, including those with co-morbidities, such as prolapse, obesity, and other types of bladder dysfunction."
Have you analyzed that?
A. Independently analyzed it, I've read the studies concerning that.
Q. You haven't read all 2,000 publications they're referring to; correct?
A. No. That is correct. Yes.
Q. It says, "It is, however, acknowledged that any operation can cause complications."
And that's a fair statement; correct?
A. There can be different sets of complications, but any procedure can have complications.
Q. "For mid-urethral slings these include bleeding, damage to the bladder and bowel, voiding difficulty, tape exposure and pelvic pain; all of

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these may require repeat surgery, but this is uncommon."
Do you see that?
A. Yes, I do.
Q. A little further down, they talk about "long-term effectiveness of up to 80 percent has been demonstrated in studies including one which has followed up a small group of patients for 17 years"; correct?
A. That's what it states, yes.
Q. And in this IUGA statement has a list of references -- do you have that? All right.
So for the 17-year study, you understand that to be the Nilsson paper on the TVT retropubic study?
A. That's the only 17-year one. I'll make an argument that it's not TVT.
Q. What argument would you make that it's not TVT?
A. Based upon the deposition by Arnaud who said it's not a TVT product. And he doesn't know if it's the polypropylene mesh even used by Ethicon -- or manufactured by Ethicon.
Q. Do you have any -- have you done any independent confirmation of whether or not that

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product was TVT other than what you just referenced with regard to Dr. Axel Arnaud's deposition testimony?
A. The only way I'd have access to that is via the deposition. It's impossible to know that in another independent source, but since Axel Arnaud is very high up in Ethicon and he states it's not TVT, I'm going to believe him.
Q. Do you know whether that mesh was a Prolene -- polypropylene mesh?
A. It was a polypropylene mesh, as what he said. Maybe made by Ethicon. Maybe made by Bard. He doesn't know.
Q. As a result IUGA supports the use of monofilament polypropylene mid-urethral slings for the surgical treatment of female stress urinary incontinence."
Do you see that?
A. Yes, I do.
Q. Do you agree or disagree with IUGA's support?
A. Disagree.
Q. You've read the AUGS and SUFU statement on mid-urethral slings?
A. Yes, I have.

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(Exhibit 10 marked.)
Q. BY MR. SNELL: You don't belong to AUGS, but you do belong to SUFU; right?
A. That -- yeah. They're sister societies. So I can attend AUGS meetings as a member, but I am not formally in their membership role.
Q. SUFU has over 500 members?
A. I don't know the number. It's a lot.
Q. AUGS -- do you know whether they represent more than 1,700 members?
A. They have a lot. They have more than SUFU.
Q. Do you have to be a urogynecologist or to have passed a subspecialty female pelvic medicine or reconstructive surgery boards to be a member of AUGS as opposed to SUFU?
A. No. You can be a member of AUGS without having any credentials. To take the board exam, the female pelvic medicine reconstructive surgery, you just have to supply certain logs, have a certain amount of volume of cases and take the exam.
Q. You took that exam and passed it; right?

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A. Correct. In June of 2013.
Q. Did you have to study for that exam?
A. Yes, I did.
Q. Did part of that exam testing concern polypropylene mid-urethral slings?
A. Yes.
Q. Was part of that exam concerning the Burch colposuspension and the autologous pubovaginal sling?
A. It's been two years, and I can't recall exactly. I know they had Burch questions and I know they had sling questions, yes.
Q. This says, "The polypropylene mesh mid-urethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence."
Do you see that? On the first page.
A. Unfortunately, no, I don't see it.
Q. Here.
A. I listen to -- oh, there on the bold. Yes. I see it.
Q. And you would agree it's within the standard of care for a female urologist or a pelvic floor surgeon to do a polypropylene mesh mid-urethral sling like the TVT retropubic today?

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A. It is not malpractice to do that procedure.
Q. It, therefore, is within the standard of care; correct?
MR. CARTMELL: Object to the form.
A. Well, as I said, it's not going to be malpractice. It is an accepted treatment out there.
Q BY MR. SNELL: You've reviewed -- well, let me ask you: Have you reviewed the AUA stress urinary incontinence guidelines?
A. Yeah. It depends which year you're talking about. There's 2009 and others.
Q. The 2009 and then the update in 2012?
A. Yes. Yes.
Q. All right. I think you pronounced the lead author's name --
A. Oh, Dmochowski. Call him Roger.
Q. For example, in those AUA stress urinary incontinence guidelines, they recognize mid-urethral, retropubic, trans -- they -- strike that.
In the AUA stress urinary incontinence guidelines they recognize the retropubic polypropylene mid-urethral sling like the TVT

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retropubic as being a suitable surgical option for surgeons to turn to; correct?
A. Yeah. Using the terminology you did, it is one of the treatment options available.
Q. And they looked at the literature, did a systematic review, and they analyzed the data on mid-urethral slings, Burch, and the autologous pubovaginal slings, and came to that conclusion?
A. Yes. They analyzed more than just those, but, yes, those are some of the ones they analyzed.
Q. Those were the main groups that they reported on; correct?
A. I'd have to look at your question -- it was, you know, retropubic, transobturator, pubovaginal, and Burch.
Q. Right. In the AUGS/SUFU statement they say, "The procedure is safe, effective, and has improved the quality of life for millions of women."
Do you see that? I'm sorry. Right where we were at.
A. Oh, I'm sorry. Yes, I see that.
Q. Do you agree or disagree with AUGS/SUFU?

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A. Disagree.
Q. You disagree that the procedure is effective?
A. No.
Q. Do you disagree that the procedure has improved the quality of lives for millions of women?
A. I have no way of proving that.
Q. You disagree the procedure is safe?
A. Yes.
Q. And do you believe that all polypropylene mesh mid-urethral slings are unsafe?
A. That are currently available on the market now, I agree with you they are all unsafe.
Q. Let me rephrase that. I don't think I asked you to agree with me.
MR. CARTMELL: You did.
MR. SNELL: No, I didn't. I think --
MR. CARTMELL: Do you disagree?
MR. SNELL: Disagree the procedure is safe, yes.
Q BY MR. SNELL: All right. My question was: And do you believe that all polypropylene mesh mid-urethral slings are unsafe?
A. Okay. All the --

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MR. CARTMELL: He answered it. Objection. Asked and answered.
We're reading it. He says that are "currently available on the market, I agree with you, they are all unsafe."
MR. SNELL: He's not agreeing with me, because I didn't posit the question as "please agree with me." I'm just asking his opinion.
Q. BY MR. SNELL: Understand. So let me just -- let's just strike that and make sure we get a clean Q and A.
Do you believe, Dr. Elliott, that all of the polypropylene mesh mid-urethral slings available for the treatment of female stress urinary incontinence are unsafe?
A. I believe that all the currently available mesh slings available on the market as of right now and their technique are unsafe.
Q. You do not disagree, I take it, that some women can have, following the TVT retropubic placement, cure of their incontinence and improvement in quality of life?
MR. CARTMELL: Object to the form.
A. It is a hypothetical individual, but there are going to be studies that show, as of

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right now, they have had -- they've reached that. The question is what will happen with long-term follow-up.
Q BY MR. SNELL: Do you only treat female stress incontinence or do you also treat male stress incontinence?
A. I treat both female and male voiding dysfunction.
Q. Do males have stress urinary incontinence?
A. Following prostate surgery. Almost exclusively that's what I see them for.
Q. Do you use any medical devices for the treatment of male stress urinary incontinence?
A. Yes. The AMS800 -- American Medical Systems 800 artificial urinary sphincter.
Q. And are there any lifelong registries monitoring those patients?
A. Yes. The AMS -- American Medical Systems keeps a registry of all implants. Every time I do a surgery on them, they are notified, and I have to fill out a summary of what I did, revision, complications, et cetera.
Q. Do those track the patients lifelong?
A. Yes.

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Q. Where is that data published, if at all?
A. It is not published. It's at AMS. American Medical Systems, which is based in Minnetonka, Minnesota. And that goes back to 1972.
(Exhibit 11 marked.)
Q BY MR. SNELL: I've handed you Exhibit 11. This is the AUGS -- one of the AUGS position statements; correct?
A. Correct. This one is on pelvic floor disorders, though.
Q. If you look at paragraph 5 where they talk about stress urinary incontinence and mesh slings.
A. On page 3, I think?
Q. Yes.
A. I'm there.
Q. It says, "Full length mid-urethral slings, both retropubic and transobturator" -- and just so we're clear, the TVT retropubic is a full length retropubic mid-urethral sling; correct?
A. I'm sorry to interrupt you. I just don't know where you are -- I see the paragraph. I just don't know which --

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Q. The bottom five, six lines.
A. Starting --
Q. Actually, the bottom three lines. That's okay.
A. Starting with "Full-length," yes.
Q. Okay. The TVT retropubic device is a full length retropubic mid-urethral sling; right?
A. Okay. I'm sorry. I was trying to find where you -- I thought you were reading. I'm sorry.
The question was, is the full-length -- well, I don't necessarily know what they mean by a full length. Everything is a full length, whether it's short or long, but this is the longest length of mesh.
Q. It says they "have been extensively studied, are safe and effective relative to other treatment options and remain the leading treatment option and current gold standard of care for stress incontinence surgery"; correct?
A. That's what they state, yes.
Q. Do you disagree or agree with AUGS?
A. I disagree.
Q. What exactly do you disagree with there in that paragraph -- sorry. In that

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sentence?
A. That is outlined in detail in my expert report, going to all those various issues.
The extensively studied, I agree with.
Safe, I disagree with, as mentioned in my expert report, my clinical experience, my discussion in national and international meetings.
Effective relative to other treatment options, I agree with. We've established that already.
Remains a leading treatment opposition, I agree. It is common, the use. I don't have a problem with that.
Current gold standard of care for stress urinary incontinence. Gold standard means absolutely nothing to me. I don't even know what that means. The term gets thrown around a lot.
Is it something that is compared to? It is the best. So it is -- I agree with the leading treatment option. There are other things that are available that it could be compared to. Burch sling or the TVT.
Q. The term "gold standard," that's something that you've seen commonly in the medical literature; correct?

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A. It is thrown around extensively. It's a bad term.
Q. You've seen people refer to the autologous pubovaginal sling as a gold standard; correct?
A. Correct.
Q. You've seen people refer to the Burch colposuspension as the gold standard; correct?
A. Correct.
Q. You've seen people refer to the TVT retropubic device as a gold standard; correct?
A. Correct.
Q. To your knowledge or understanding, is there a -- strike that.
To your knowledge and understanding, what does it mean to be a gold standard within the art of pelvic surgery?
A. It should be -- this is my interpretation of it.
Gold standard should be the procedure that has the safest, the best, which everything should be compared to. The gold standard, unlike gold. Gold cannot -- the true iron -- or true element cannot be replaced. Okay. Gold standards have evolved.

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In the '90s, it was the Raz, R-a-z, urethropexy. That's gone now. So gold standard is a shifting thing. It's what everything should be compared to because it has proven itself to be the best in all factors involved.

Q. Back when the Raz urethropexy was reported in the literature, there weren't any randomized control trials in that procedure, comparing it to the Burch and pubovaginal sling; correct?

A. I'd have to look at the literature. I don't recall any.

Q. Did people refer to, like, the Raz procedure as the gold standard, not based on comparative -- direct comparative data?

A. The gold standard relative to urinary incontinence has really evolved since TVT came out. And that's when there was now a comparison. You had some people were for Burch, some people for sling, some people for the Raz. The Raz fell out. Wasn't effective. Then TVT was around. Then the argument came of this gold standard. But, again, it's not like you can type up a paper and put in equations and come up with, oh, this one's gold. It's relative.

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Q. There are other procedures for stress urinary incontinence that have also fallen out of favor, like the MMK that you earlier referenced; correct?

A. Correct. There are many that have faded away.

Q. The anterior repair is another; correct?

A. Well, I don't know if you're talking about the Kennedy Kelly plication. That is still done somewhat, but it's not, what you would say, in the upper tier of effective treatments.

Q. And that would be based on randomized control trial data or cohort studies?

A. Cohort studies.

MR. SNELL: Let's mark this as the next one.

(Exhibit 12 marked.)

Q BY MR. SNELL: Exhibit 12 is the EAU Guidelines on Surgical Treatment of stress -- strike that.

EAU Guidelines -- let me get a better question out.

Exhibit 12 is the EAU Guidelines on Surgical Treatment of Urinary Incontinence;

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correct?

A. That is correct.

Q. And have you reviewed this document before?

A. Yes, I have.

Q. Okay. Were you involved in the drafting of this document?

A. No, I was not. And the interesting thing is, being a member of the female urology section, I don't recognize very many of these names.

Q. This was published in 2012; right?

A. Yes.

Q. And what they did was, using their methodology, they used evidence-based medicine methodology and did individual literature search strategies?

A. Correct. For the treatment of both men and women.

Q. Fair enough.

And for the treatment of stress urinary incontinence in women, they concluded that mid-urethral slings should be offered as the first line treatment; correct?

A. I'd have to see where you're quoting.

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I just don't see it in the document. The document's fairly long.

Q. Okay. The third page, go to the surgical algorithm.

A. Yes.

Q. Where you see if a person has -- a woman; right? The top diagram is for treatment in women; right?

A. Correct.

Q. And for stress incontinent women, first line is "Offer mid-urethral sling"; correct?

A. Yeah. Or "consider peri-urethral injections"; right.

Q. Right. So mid-urethral sling would be a first-line surgical option for the treatment of stress urinary incontinence in women, according to the EAU Guidelines; correct?

A. Yeah. Yes. This algorithm, established in 2012, that is what they offer as first-line treatment.

Q. And they also identify the mid-urethral sling as a first-line surgical option if there's mixed incontinence, but the stress is predominant; correct?

A. Yes.

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Q. And do you disagree with the EAU Guidelines in that regard?
A. Yes, I do.
(Exhibit 13 marked.)
Q BY MR. SNELL: This is the Guidelines on Urinary Incontinence from the EAU 2015.
Do you see that?
A. Yes, I do.
Q. So this is when you were in your role in that pertinent group; correct?
A. That's correct.
Q. First page says, "Mid-urethral slings are now the most frequently used surgical intervention in Europe for women with stress urinary incontinence."
Do you see that?
A. I don't see it. But I heard you read it. Okay. Yes. Yes, I see it. Yes.
Q. And for the purpose of the guidelines, they did a new meta-analysis; correct?
A. Correct.
Q. Were you consulted on these guidelines?
A. No, I was not.
Q. But these are people who are in the

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group that you belong to?
A. They're in -- members of the EAU. But these are not people in the subsection of female urology and functional urology. And I'm on the board of those. And I know some of their names, but they're not sitting on the board.
Q. Were you even aware that these urinary incontinence guidelines were published in 2015 by EAU?
A. No. I was aware they were published. I was not part of their publishing.
Q. Does the EAU still recognize the mid-urethral polypropylene slings as a surgical option to treat stress urinary incontinence?
A. Yes. As stated in their document, they do not ban its use.
Q. Do they still, as of today, recognize the mid-urethral polypropylene sling as being the appropriate first-line surgical option?
A. That's what they state in the previous document. I don't know about this one.
(Exhibit 14 marked.)
Q. BY MR. SNELL: So these are the fact sheets by ICS published July 2013.
Do you see that?

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A. Yes, I do.
Q. ICS is another organization you belong to; correct?
A. That is correct.
Q. And so they cover different conditions, like overactive bladder, and then they have stress urinary incontinence beginning on page 12.
A. Yes.
Q. Have you seen these before?
A. Um-hum. Yes, I have.
Q. Do you use these statements with any of your patients?
A. No.
Q. I know ACOG and the Urology Foundation, the branch of the AUA, have patient guides, publications, things like that.
Do you use any of those materials with your patients?
A. We have them available for education purposes. We'll go through it. But to be honest, usually that's so overwhelming for the average individual that we don't rely on them heavily.
Q. Does Mayo Clinic have its own patient education handouts that you use --

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A. Yeah. We have a --
Q. -- for stress urinary incontinence? That's what I'm focused on.
A. We have an overarching, for incontinence. Within it is a subsection of stress incontinence. But it's not specific just to stress.
Q. Okay. On page 13 where they're talking about -- it says, "Definitive therapy for SUI is surgical."
A. Correct.
Q. You would agree with that; correct?
MR. CARTMELL: I'm sorry. What was the question again?
A. Definitive area for SUI is the surgical?
Q. BY MR. SNELL: No. Let me repeat it. It's not "area."
This states on page 13, "Definitive therapy for SUI is surgical."
Do you see that?
A. No. I see it.
Q. Do you agree with that?
A. I'd say no. It is -- surgery is an option for some individuals. But some individuals

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with appropriate counseling do not need to have surgery. So depends how you're defining definitive, I suppose. There are other things that work.

Q. Right. So pelvic floor exercises; correct?

A. Correct. That's one of them.

Q. And bulking agents; correct?

A. Correct.

Q. And you're aware of data showing surgical -- when you compare stress urinary incontinence surgery, the efficacy of that compared to those alternatives, non-surgical alternatives, surgery has better results?

A. Correct. I agree with that. I just have a problem with definitive therapy.

Q. Right.

A. It's a little too dogmatic for me.

Q. Okay. "Worldwide, mid-urethral slings comprised of synthetic mesh have become the treatment of choice for SUI."

And we've already discussed that; right?

A. Ad nauseam, yes.

Q. "Long-term data are robust and

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demonstrate durable efficacy with a very low complication rate, particularly in experienced hands."

You would agree with that?

MR. CARTMELL: Object to the form.

A. I agree with parts and disagree with other parts. So in totality, I would have to say I disagree.

Q BY MR. SNELL: What do you agree with in that sentence?

A. Long-term -- oh, what do I agree with? Sorry.

Q. Yes.

A. I think, as we established, "durable efficacy," I'm okay with that.

And then, "particularly in experienced hands," as I've stated before, more experienced surgeons, the data is very clear. Arnaud even admitted they're going to have better results.

"Very low complication rates," I disagree with. Strongly.

Q. For any type of stress incontinence surgery, we can agree that more experienced surgeons are going to typically give better results; right?

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A. Yes, that is a fair statement.

Q. And I mean, you're a better surgeon, don't you think, today than when you were coming out of your fellowship; correct?

A. Correct.

Q. And part of that is because you've amassed more surgical volume experience; correct?

A. That is one aspect of it. And I have read hundreds of journal articles, attend all the national and international meetings, and discuss with high level colleagues. But, yes, there should be progress. But individuals who don't have the advantages I do, aren't necessarily going to progress. They could actually worsen.

(Exhibit 15 marked.)

Q BY MR. SNELL: This is the NICE, N-I-C-E, Clinical Guideline 171 issued September 2013 on urinary incontinence in women.

Are you familiar with this?

A. Yes, I am.

Q. Turn to page 24.

A. Okay.

Q. And just as background, you're aware then that in the generation of this NICE guideline they searched the medical literature?

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A. Yes. They have done similar to what the AUA guidelines are. All these societies do essentially the same thing.

Q. And they say for when offering -- strike that.

They state, paragraph 1.10.3, "When offering a synthetic mid-urethral tape procedure surgeons should: Use procedures and devices for which there is current high quality evidence of efficacy and safety."

Do you see that?

A. Yes, and I agree with that statement.

Q. They also say use only -- "only use a device that they have been trained to use."

Do you agree with that?

A. Yes, I do.

Q. Do you use any devices that you weren't trained on?

A. No.

Q. "Use a device manufactured from type 1 macroporous polypropylene tape."

Do you agree with that?

A. If he's referring to the Amid type 1, I disagree with that.

Q. Well, there's no other type 1 system

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that reports and identifies macroporous versus microporous than Amid; correct?
A. There is no industry standard regarding that. However, I'm stating that Amid is archaic. So macroporous is a relative term. We have to define what macroporous is.
Q. So there is no -- so macroporous means macro, large; porous, pores; correct?
A. That is the literal translation of the word, yes.
Q. And in the Amid classification, macroporous is defined as greater or equal to 75 microns; is that correct?
A. Yeah. Yeah. Greater than or equal to, yeah, that's what Amid does.
Q. And that's because the cells involved in tissue ingeneration, combating bacteria are all cells that are smaller than 75 microns; correct?
A. Well, I mean, it goes beyond that, that the 75 microns and be able to have the inflammatory responders, be able to perforate through that.
But, again, the data shows, Ethicon agrees as stating, that it's 1,000 microns now and a minimum under strain. So what I'm saying is the

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Amid is archaic, and not the standard used anymore.
Q. Do any of the professional societies that you belong to state and define macroporous as anything other than that which the Amid classification states it as, greater than or equal to 75 microns?
A. I have yet to see that in any of the society statements that they state that because they don't know the information I've been privy to.
Q. We can agree that those inflammatory cells are all smaller than 75 microns; correct?
MR. CARTMELL: Object to the form.
A. Not necessarily, because some of the macrophages, especially under activated states, can be up to 80 micrometers or greater.
Q BY MR. SNELL: Well, you know macrophages can enhance pseudopodia, which can get into spaces that are less than 5 microns; don't you.
A. Then if all that were true --
Q. Answer my question. Do you know that or not?
A. I was answering your question.

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MR. CARTMELL: Let him answer.
A. And I'm saying, if all that were true, we would not be sitting here with all the degradation problems and inflammatory responses. And then I know what I read with Ethicon depositions, that they all agree that is too small and that is not the standard they go by. So all I'm saying is I do not agree with this as it's stated.
Q BY MR. SNELL: But my question to you is: Based on your knowledge and scientific understanding, can macrophages extend pseudopodia to try to get to bacteria in spaces less than 5 microns?
A. They can try, but are they successful?
Q. Are they --
A. And this is -- this is 75 microns when it comes out of the box. But that's not under stress. So it decreases. So, again, where they're really insufficient and where I have privy to information is not what it comes out of the box, when it's been implanted in the woman and after contraction of scarring.
Q. The pore size in the mesh for TVT is much larger than 75 microns out of the box. We

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can agree to that.
A. Out of the box, I have seen numbers all over the board because they don't have a -- there's not a circle with a diameter. There's wires or fibers going everywhere. So there's not a uniform size. So you may have one greater than 75. Right next to it, you have one at 10 microns. And that's what P.A. Newell said under oath.
Q. Have you ever put the TVT mesh out of the box next to a millimeter ruler and looked --
A. Yes.
Q. -- and seen whether the pores are larger than a millimeter?
A. Absolutely, I have.
Q. And those pores are larger than a millimeter out of the box; correct?
A. Absolutely not. A millimeter?
Q. Yes. 100 microns for a TVT.
A. Out of the box. You might be able to find some, but right next to it it's not. But, again, that doesn't matter out of the box. It's when it is implanted in the woman under load.
Q. Yes. But those inflammatory cells don't just go in circles; do they, sir?
A. Well, there's going to be

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literature -- and let's go to my expert report on this, on degradation and pore size. I've got the literature stated from individuals like Klinge, Klosterhalfen, Costello, Clave, et al., who will disagree with you, that, no, that pore size is insufficient to have adequate tissue incorporation and prevention of the inflammation which then causes degradation, et cetera.

Q. Klinge and those doctors were assessing hernia mesh, not the TVT device in the application of stress incontinence in women; correct?

MR. CARTMELL: Object to the form.

A. Okay. And then --

Q BY MR. SNELL: Is that a yes or no?

A. No. I can't answer a separate yes or no because my understanding is they're doing hernia meshes in the abdomen. TVT is a hernia mesh being put into the vagina. So it's going to be a worse of an environment because of higher bacteria counts. Different types of strain. So if it performs poorly in the abdomen, it's going to perform worse in the vagina.

Q. All of the citations where you cite to Klinge and those doctors in your report are in the

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context of hernia; correct?

A. All right. Let's go to my expert report on pore size, because if we're going to talk about this in detail -- I spent a lot of time on this, and so we can go to that. So I have it down here beginning around page 18, where I reference internal documents, studies, et cetera.

Q. None of them being TVT retropubic device studies that were in women; correct?

A. Well, if --

Q. That's a yes or no. So which one is it?

MR. CARTMELL: No. You can answer. Let him answer. You cut him off again. That's twice in the last minute and a half.

MR. SNELL: No, no. I can say a yes or no question, Tom; you know that.

MR. CARTMELL: So let him answer the question. Go ahead.

MR. SNELL: It's a yes or no.

MR. CARTMELL: Go ahead.

A. They have done studies looking at the hernia mesh. Have Klinge, Klosterhalfen and others done it specifically with the TVT? No. But I have to extrapolate the data. That would

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have been something very good for Ethicon to have done.

MR. SNELL: Move to strike everything up to the responsiveness about "when they" with regard to TVT, no.

Q. BY MR. SNELL: You call him Klingel.

A. Klinge.

Q. Is it Klingel or Klinge? Because I heard it all different ways.

MR. CARTMELL: I thought it's Klinge.

A. It's Klinge.

MR. CARTMELL: Klinge, okay. He said Klinge.

Q BY MR. SNELL: Oh, I think he said Klingel, like Chris Klingel? I just want to make sure I know we're talking about the same person. It's the same person; right?

A. Klinge, yeah.

Q. Okay. Look, I'm even worse than you are with names, and you're pretty good with names. I'm bad with them. All right.

MR. CARTMELL: Chris Klinge.

Q BY MR. SNELL: So we were looking at that NICE guideline. It says down --

MR. CARTMELL: NICE or NICE.

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Q BY MR. SNELL: That's a good one. It's abbreviated NICE.

A. I know it.

Q. All right. So for the NICE guideline under colposuspension, it says, "Do not offer a laparoscopic colposuspension as a routine procedure for the treatment of stress UI in women."

Do you see that?

A. Yes, I do.

Q. You've never done a laparoscopic Burch; right?

A. No, I have not.

Q. Why would they say that respect to the laparoscopic Burch?

A. Well, the laparoscopic Burch is really not a -- let me start over.

A laparoscopic Burch is not a true Burch procedure. They have to modify it, and it's not really even a Burch. And the success has been poor with the laparoscopic procedure called the laparoscopic Burch.

Q. Under Biological slings they say, "Do not offer anterior colporrhaphy, needle suspensions, paravaginal defect repair and the MMK

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for the treatment of stress UI."
Do you see that?
A. Yes, I do.
Q. Is that an accurate, up-to-date statement with regard to the practice of surgically treating female stress urinary incontinence?
A. This is a very simplified, infantile form of it, but anterior colporrhaphy is to treat prolapses, not incontinence.
Q. Okay.
A. Needle suspensions have fallen out of favor because they don't work. Paravaginal defect repair, it's, again, a prolapse repair. It's not incontinence. MMK, in the correct the high-volume surgeon's hands can have decent success with it, but that's not everybody. So I agree that it's not going to be, by any means, for the overwhelming majority of people a first-line treatment.
Q. Is the MMK taught at all to residents and fellows in Mayo?
A. In the GYN department it may be, but not in urology at all.
Q. Do you think it's a fair statement

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that as between GYNs versus urologists, GYNs tend to do more colposuspension procedures than urologists, like yourself tend to favor slings more?
MR. CARTMELL: Object to the form.
A. Colposuspension just means a vaginal prolapse repair. So that's what you're talking about. They do more prolapse than we do?
Q BY MR. SNELL: No. They do more like Burch and MMK?
A. Oh, yes. Oh, okay. I see what you're saying.
That would probably be a fair statement, yes.
(Recessed from 1:45 p.m. to 1:50 p.m.)
(Exhibit 16 marked.)
Q BY MR. SNELL: Doctor, I've handed you Exhibit 16. This is from the Mayo Clinic regarding urinary incontinence.
Is this the information you had earlier referenced that Mayo puts out regarding urinary incontinence?
A. Well, this is on their web site, yeah, which I had no role in this.

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Q. I printed this out September 18th, 2015. You see that at the bottom?
A. Yes.
Q. This is where the Mayo Clinic is talking about urinary incontinence, particularly for women; right?
A. Yes.
Q. And you see on the second page, Mayo Clinic.
And you still work at Mayo Clinic; right?
A. Correct.
Q. Talks about "Sling procedures to treat stress incontinence"; correct?
A. Correct.
Q. And they say Mayo Clinic -- are you employed by Mayo Clinic or are you an independent contractor?
A. No. I'm employed by Mayo.
Q. Mayo Clinic says sling procedures and bladder neck suspension procedures are the most common surgical procedures; right? Falling into those categories?
A. I don't see where you're reading from.
Q. Let me withdraw. Restate it.

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MR. CARTMELL: Where's it say that?
Q. BY MR. SNELL: The topic under Sling procedures to treat stress incontinence on page 2. Are you there?
A. Yes.
Q. All right. And Mayo Clinic, your employer, says, "Most surgical procedures to treat stress incontinence fall into two main categories: Sling procedures and bladder neck suspension procedures."
A. That's what it states, but the Mayo Clinic doesn't state anything. It's a building. So this is a writer that has been hired to do this, which I had no role in, but that's what they state there.
Q. Well, Mayo Clinic doesn't put unreliable information on their web site to patients; do they?
A. No. Again, I'm saying, Mayo Clinic is a building. So I'm saying it's like saying the White House said something. Well, no a person said it.
But I'm saying, this is what is stated on the Mayo Clinic web site.
Q. Right. And it says, "During a sling

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procedure, your surgeon uses strips of synthetic mesh, your own tissue or sometimes animal or donor tissue to create a sling or 'hammock' under your urethra or bladder neck; correct?
A. Correct.
Q. And that's accurate; right?
A. That is correct; yes.
Q. Depending upon which option a surgeon chooses to offer to his or her patients; correct?
A. That's correct; yes.
Q. "The sling procedure that's best for you depends upon your individual situation," it says.
You'd agree with that?
A. Correct.
Q. It's got Tension-free sling under that. You with me?
A. Yes.
Q. "No stitches are used to attach the tension-free sling, which is made from a strip of synthetic mesh tape"; correct?
A. Correct.
Q. And that's like the TVT retropubic device; correct?
A. That would be one of them, but there'd

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be a lot in that category, yes.
Q. "Instead, body tissue holds the sling in place"; correct?
A. Correct.
Q. "Eventually scar tissue forms in and around the mesh to keep it from moving."
That's correct?
A. Yeah. That is part of the problem, but, yes.
Q. And then they talk about retropubic and transobturator approaches that we've discussed today; right?
A. Correct.
Q. Then on the next page, the Mayo Clinic says, "Using surgical mesh is a safe and effective way to treat stress urinary incontinence."
A. That is what --
Q. You agree with that; right?
A. I disagree with that.
Q. So you disagree with your employer, the Mayo Clinic, that surgical mesh is a safe and effective way to treat stress urinary incontinence?
A. And it says, "However, complications can occur in some women, including erosion of the

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material, infection and pain."
That part I agree with. But in my department, in Urology, no one uses meshes, except for me one time in the past 2-1/2 years. I cannot speak for the gynecologists. But I was not part of writing this document.
Q. So you disagree with the Mayo Clinic's web site.
MR. CARTMELL: Object to the form. He has already answered that question. Okay? You asked him specifically what the web site says. He said he disagrees with it. So don't answer that.
Q BY MR. SNELL: How about this? A little further down it says, "A conventional sling sometimes requires a larger incision than a tension-free sling. You may need an overnight stay in a hospital and usually a longer recovery period. You may also need a temporary catheter after surgery while you heal."
You agree with that; right?
A. Yes.
Q. Do you teach your patients for whom you do an autologous sling self-catheterization?
A. No.
Q. You had mentioned -- we were talking

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about -- strike that.
We were talking about the 17-year paper by Nilsson, et al.?
A. Correct.
Q. And you had said you were not sure as to whether that study followed patients who had received the Prolene mesh?
A. Oh, I said Arnaud was not sure, and so subsequently I'm not sure.
Q. I'm not asking about Arnaud. I'm asking you.
A. I was clarifying.
Q. Okay. So what was your methodology in selecting that one quote out of Arnaud's multiple days of testimony?
MR. CARTMELL: Object to the form. I'm not sure what you mean.
A. My methodology was, in this one very straightforward. I read the deposition. They asked Arnaud questions, is this TVT, and he says, no, similar, but it is not TVT.
They say, is this polypropylene Ethicon, and he says, to the effect, no it could be ours. It could be Bard's. I don't know. So methodology on this one is straightforward.

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Q BY MR. SNELL: So you believe the testimony was in -- that he gave was in regards to the Nilsson study?
A. In the original Ulmsten study that has subsequently been carried forward to 17 years.
Q. Let's mark that.
(Exhibit 17 marked.)
Q BY MR. SNELL: You recognize this, Doctor, to be that same study we've been discussing by Nilsson, et al.?
A. That is correct. That is a --
MR. CARTMELL: The 17 year?
A. That's what I'm trying to find out.
MR. CARTMELL: This isn't the 17 year. This is 2000 --
A. This is 2001.
Q BY MR. SNELL: Right. This is the same study, but it reported that the mean follow-up of 56 months; right?
A. Correct. I don't know what -- I don't see what the follow-up was on this one. Was it the 5 year?
Q. It's right here. It's right here. Yeah. Yeah.
A. It's the 5 year. Approximately 5 year

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range. Yes.
Q. Right.
A. This is the 5-year study.
Q. You're familiar with this. They follow the series at 5 years, 7, 11, and 17 years; correct?
A. Yes, sir.
Q. All right. And if you go to the Patients and Methods section, in the left column it says, "The TVT set consisted of two 6 millimeter needles connected to a handle and a specific polypropylene (Prolene) mesh tape fixed to the needles."
Do you see that?
A. Yes, I do.
Q. So this paper reports that the mesh they used in that Nilsson study was Prolene tape; correct?
A. Even the medical director of Ethicon needs to get updated on his data. I don't know why he would raise those issues then, because he was there during this time frame and involved, as far as knowledge of these studies. So that would have to be answered by him. But he said it under oath. So all I'm doing is parroting back what I

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have read him say.
Q. Right. The jury can ultimately hear testimony and decide whatever they want to.
A. Correct.
Q. But for you as a doctor, this is medical literature. Did you read this and ignore it or did you not know about this?
A. Oh, I knew it. I knew it very well. I read all these, including the 17-year one. I also know that Ulmsten was paid $400,000, which Arnaud said was a conflict of interest and would bias the results. I also know from other things that they don't necessarily write down what the truth is. All I know is the authors were getting paid $400,000 originally and are getting money, save TVT. The medical director of Ethicon says, I don't know if it is, maybe not, but it's not TVT.
Q. And you chose to go with the medical director?
A. No, I'm keeping an open mind. I have to have data to show me clearly that this was. Because from my perspective from what Arnaud said, who should be the authority, this is a Mediscan product, and or possibly Bard mesh. So it raises a major problem for me. And I am not -- if you

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show me -- if you have data to prove it, I would love to see it.
Q. You mentioned the $400,000 that Ulmsten received. Why does that matter to you?
A. Well, conflict of interest and bias, unfortunately, exists in medicine. And that's why now we have to declare that. Originally we did not have to declare it. During my residency you didn't have to do it. Early on in staff, you didn't have to do it. But because of events like this, now you have to declare it.
So if there is money and you stand to make a lot of money, there's the potential for bias. I didn't say there is there. I said there's a potential for it. There's clearly a conflict of interest, which Arnaud agreed with me on that. He said there is conflict of interest in this paper. So that is important. You have to read this article through that lens of potential bias.
Q. And the same would hold true for all the Vypro and other studies you cited by Dr. Klinge who had a financial interest, correct, in promoting that product.
A. You --

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MR. CARTMELL: Wait. Object to the form. It's vague and ambiguous with respect to what product you're talking about.

MR. SNELL: I said Vypro; didn't I?

Q. BY MR. SNELL: You know Dr. Klinge had an interest in Vypro, don't you, Doctor?

A. I do know that.

Q. You know he's biased with regard to Vypro; don't you?

A. No. There's a difference between conflict of interest and bias. I am stating with Nilsson and Ulmsten there is a conflict of interest. There is the potential for bias. I didn't say there was bias. And as a reviewer, I have to keep an open mind and look at that. I'm not denying at all with the Klinge, Klosterhalfen, whichever one -- I can't remember which one's which. But with Vypro, if there is a financial interest there, that is a potential for conflict of interest. If there is a conflict of interest, potential for bias.

Q. All right. And you know for a fact that exists with Dr. Klinge?

A. I don't know for a fact. I can't keep track of who's got what where. But if you are

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stating for me that he has a financial interest in that, that does -- I have to be concerned about that and look at it as objectively as I can.

Q. And you cited to Dr. Klinge more than 10 times in your expert report; right?

A. Probably. And I also cite the Nilsson and Ulmsten studies quite a bit in there, too. Those are all the body of evidence in the methodology that I have to look at is look at the potential for bias in papers.

Q. Tell me if you agree or disagree with these assertions. The Burch and MMK are very invasive, often result in complications, and usually require prolonged hospital stays.

A. A lot of factors. It would be easier if we go one by one or if you just want to -- if you want to take the sentence in totality, it all has to be true, I disagree with it. We can go bit by bit through it, though.

Q. You would agree that Burch and MMK both are very invasive?

A. I disagree. Compared to what?

Q. Compared to alternative surgeries for stress urinary incontinence.

A. No. Now, you've lumped MMK and Burch

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together. So that's not a fair comparison. The Burch can be done -- you can get it done in a 5, 6, 7-centimeter incision. Outpatient, overnight stay in the hospital. So, no, I disagree with that. There are studies out there showing longer stays. It's all over the board.

Q. But you'd at least agree with the statement that the pubovaginal sling is effective but is known to have a high rate of complications, require long hospital stays, and patients often experience a significant amount of pain?

MR. CARTMELL: Object to the form.

A. Again, we're looking at the perioperative period. So I would agree with that, but we have to always compare it to what. Are we comparing it to TVT? Are we comparing it to the synthetics? Are we comparing it to the MMK or just any transabdominal procedure?

Q BY MR. SNELL: You would agree with the statement that mid-urethral sling procedures are much less invasive than the earlier pubovaginal sling procedures; right?

A. Overall, when you're doing a comparison of synthetics to the pubovaginal or Burch, those are -- the Burch and pubovaginal

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slings are going to be relatively more invasive.

Q. Would you agree or disagree with the statement that tension-free mid-urethral sling, like the TVT retropubic, is a significant advancement in treating stress urinary incontinence?

A. Oh, yes. And early on I was very -- now, again, I never used the TVT because I was described the various different fears of it. But when TVT came out, it was revolutionary. It changed the way we did things. But we didn't know what we know now. And even comparing myself to two or three years ago, my opinion has changed. So, yeah, it was touted as being revolutionary.

(Discussion off the record.)

(Exhibit 18 marked.)

Q BY MR. SNELL: Doctor, I've given you the Cochrane Review. This is the publication in 2011.

A. Correct.

Q. You're familiar with this; correct?

A. Yes, I am.

Q. And this was the Cochrane Review where they did a comparative analysis of like the retropubic TVT versus the Burch or pubovaginal

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slings; correct?
A. I see suburethral slings, open retropubic colposuspension. I don't see pubovaginal in there. I'm not saying it isn't there. I just don't see it.
Q. Well, here, let's -- let me just -- we'll go through it quickly. In the Results section -- I'm on the very front. They say, "Minimally invasive synthetic suburethral sling operations appeared to be as effective as traditional suburethral slings"; correct?
A. Correct.
Q. And when they talk about traditional suburethral slings, that would be like the autologous pubovaginal sling; correct?
A. That's not nomenclature that's normally used. It's not called a suburethral sling. I would have to see what they're referring to. It's called a pubovaginal sling. It's not -- suburethral slings, normal nomenclature is the synthetics.
Q. On the next page where they go through the different procedures, they put the -- what I read to be the pubovaginal slings and the minimally invasive slings, like TVT, under the

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category of suburethral slings.
Do you see that?
A. Yeah. What they're doing is they're comparing it to the colposuspension, which would be probably supra urethral slings -- or supra urethral suspension. That's probably what they're doing.
Q. Okay. But they found that "the minimally invasive synthetic suburethral slings appeared to be as effective as the traditional suburethral slings, but with shorter operating time and less postoperative voiding dysfunction and de novo urgency symptoms; correct?
A. Okay. That's what they state, yes.
Q. And have you seen data consistent with that conclusion by this Cochrane Review?
A. I've seen data consistent with it and inconsistent with it. So, again, I'd have to analyze each of the studies, what they're talking about.
Q. Have you seen any other meta-analyses that report that for the TVT retropubic compared to pubovaginal slings, it has a higher rate of complications?
A. Again, I'd have to see the -- I don't

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recall seeing another meta-analysis. And, again, then I'd have to look at how long the follow-up is. Is it 12 months or is it 30 years. That's what matters to me, end of the patient.
Q. "Minimally invasive synthetic slings appeared to be as effective as the open retropubic colposuspension."
A. Yeah. I don't see where you are. And I wouldn't challenge --
Q. I wouldn't mislead you. I'm just reading --
A. No. I don't doubt. That's what we've been discussing all along. The Burch and the pubovaginal sling and the TVT have many studies showing they have similar efficacy.
Q. And here's what I want to ask you about.
But the TVT retropubic sling "has fewer perioperative complications, less postoperative voiding dysfunction, shorter operative time and hospital stay, but significantly more bladder perforations."
A. Correct. And the key with that statement, as you read it, was perioperative. So that's immediate perioperative. And I'm not going

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to challenge. I think it's going to be somewhat of a relative issue. It's the long-term complications that I'm most concerned about and see on a daily basis in my clinic.
Q. So in the comparative studies for like comparing to the Burch, there are some perioperative complications that appear to be higher with Burch as compared to the TVT; correct?
A. Correct.
Q. Bladder perforation being the one higher with the TVT because of the retropubic passage; correct?
A. Correct.
Q. A little further down they say that the "retropubic bottom-to-top route was more effective than the top-to-bottom route"; correct?
A. That was their conclusion. It says effective in -- it doesn't say exactly here, but I assume they're talking about stress urinary incontinence. That's what they state.
Q. That's consistent with the Ford paper you cited; right?
A. Yes.
Q. And the approach used by TVT retropubic "incurred significantly less voiding

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dysfunction, bladder perforations, and tape erosions"; correct?
A. That's what they state, yes.
Q. That's consistent with the Ford paper; right?
A. I'd have to look back at that, but it sounds similar.
Q. "Monofilament tapes had significantly higher objective cure rates compared to multifilament tapes and fewer tape erosions."
Do you see that?
A. Yes.
Q. And TVT is a monofilament tape; correct?
A. Correct.
Q. And that's a benefit of monofilament tapes over multifilament tapes, where they have fewer erosions; correct?
A. Yeah. The multifilament is going to be a worse product. Doesn't mean monofilament is safe. It just says is safer relative to the worst product. Worse --
Q. And the -- I'm sorry. You're going --
A. No, no, no, no.
Q. And the monofilament tape had a rate

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of erosion of 1.3 percent; correct?
A. Based upon their analysis here in the hands of experts and short-term follow-up, yes, that's the number they found.
Q. Were you aware of this Ogah/Cochrane Review at the time you wrote your draft -- your expert report?
A. I don't recall when I became aware of it. It's a -- it's a well-known paper.
Q. In looking at your report, I did not see you citing to any TVT retropubic device literature where the device had been used to treat stress urinary incontinence in women and where it was reported that there was contraction.
Is that a fair statement with regard to your report?
A. No. That would be incorrect.
Q. Where in your report do you report studies in TVT in women that reports contractions?
A. Well, wherever there is pain, wherever there is extrusion, that is evidence of contraction.
Q. Where in your report do you report that?
A. Well, if we go to pain or dyspareunia.

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Let's see here. There's Kuhn, et al.
Q. Let me see where you're at.
A. Which is a TVT paper. Let me see where Kuhn is referenced. I'd have to search for it.
Q. Just so I'm on the same page as you, Doctor, I appreciate you telling me what page of your report you're on where you discuss contraction with the TVT. I'm going to let you -- let's take a quick break.
(Recessed from 2:17 p.m. to 2:28 p.m.)
Q BY MR. SNELL: All right. Okay, Doctor, before we took a break, I asked you to show me in your expert report where you discuss contraction rates with regard to the TVT device and its use in women for stress urinary incontinence.
Can you point me to that?
A. Well, in the Contraction section, obviously we do a lot of discussion about contraction, various different studies with it. When we limit it specifically to TVT, I think we have to look at Wang, et al., on page 24, where we're talking about infections, erosions and

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exposures, because the complication of contraction is intimately tied to also exposures and infections.
Q. So TVT and contraction -- strike that.
So for TVT contraction in women, you point me to Wang on page 24?
A. That's when you specifically limit it just to the TVT product.
Q. Right.
A. Because as I mentioned, all complications are all intertwined. So exposure, infection is intertwined with inflammation, contraction, degradation, et cetera.
Q. And the other part of your report where you talk about contraction, you talk about Klinge and his discussion of hernia mesh contraction; right?
A. That is correct, because that is a TVT mesh implanted via the abdominal route.
Q. All right. It's not cut to and configured as TVT is; correct?
A. No. But without -- no, you are correct. However, the TVT mesh has different forces placed upon it that the hernia meshes do not, i.e., you can make hernia meshes lay flat.

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You can't do that with the vagina.
Q. The hernia mesh does not have a sheath on it; correct?
A. No. It does not, but it's also not placed in the vagina to have bacterial contamination.
Q. When you say bacterial contamination, you're not referring to infection; are you?
A. I'm referring to bacterial contamination.
Q. Right. There is a difference between bacterial contamination and infection; correct?
A. Yes, but infection starts with a contamination.
Q. Right. You're aware of the paper by Pat Culligan where they found and they quantified the different bacteria counts in the vagina?
A. Correct.
Q. In that study there were patients who received the TVT as well; correct?
A. I'd have to look at it. I don't recall the specifics.
Q. Would it surprise you to learn that there were no infections with the TVT mesh in the Culligan paper.

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MR. CARTMELL: Object to the form.
A. I would have to look at the methodology, because methodology is very important. I'd have to look at how they did the study and what they looked at.
Q BY MR. SNELL: Have you looked at that?
A. Yes, I have, but I don't have it off the top of my head.
Q. Is it your opinion that whenever mesh is placed through the vagina there is bacteria that gets on it?
A. We know that the vagina's impossible to sterilize, and so when you place it through the vagina, you are going to have contact with that. So it's even with the sheath on it, but then when you remove the sheath, there's going to be issues there. So the risk for contamination on every single one is definitely there.
Q. But that does not translate into infection?
A. It might not translate into a clinical infection/abscess, but it can correlate to a subclinical infection, leading to inflammation, degradation, and that cascade.

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Q. And you have not stated in your report the rate at which clinical infections occur with TVT; have you?
A. I don't recall that specific, but the way you phrase it, specifically mentioned in there.
Q. I have not seen in your expert report where you calculate and state the complication rates with the TVT retropubic device.
A. Because we don't know the true complication rate. We can quote studies, as I mentioned, in high volume surgeons with limited follow-up. We can quote those. But as I said, we don't know the true complication rate.
Q. Well, there are meta-analyses, and we've gone through a couple of them today and various other studies that report rates of complications, and you're aware of that; correct?
A. Yes. But that does not reflect what is happening out in the real world and what I see in my daily practice. That the average low-volume surgeon, who does the majority of the TVTs in the United States, that's what -- you know, because Arnaud even admitted, their complication rates are even going to be higher. So, yes, we can quote

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extensively the studies that you've done that show these various different complication rates with short-term follow-up and highly experienced surgeons.
Q. In the studies that report on the TVT retropubic device, what percentage of those studies involved surgeons who were of average quality?
A. Well, I can't speak to quality. All we can speak to is volume.
Q. How many of those then had average volume for the TVT retropubic studies?
A. Most likely very few of those had small volume. And the Kuuva study, they eliminated the lower volume studies -- lower volume people. So they falsely raised their success rate and lowered their complication rate. But, no, small volume surgeons aren't going to publish anything because they're small volume.
MR. SNELL: Move to strike.
Q. BY MR. SNELL: Do you know of all the TVT retropubic device studies which percent of them included surgeons that had average volume or less?
MR. CARTMELL: Object to the form.

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Asked and answered. He said a very small percentage of those. He answered your question. He also said other information, but he specifically answered your question. So please move on.

Q BY MR. SNELL: Is that correct; you believe it's a very small number?

A. Average or low-volume surgeons aren't going to have their data included because they don't have enough data to analyze.

The only way I can answer your question is Kuuva, et al., where they actually eliminated the small volume surgeons who had done less than 15.

Q. I'm familiar with the Kuuva paper. I'm talking about the hundreds of other TVT retropubic papers. In those, is it correct that you don't know what percent of those papers reported on surgeons who had average to low volume?

MR. CARTMELL: Objection. Asked and answered. You can tell him again.

A. As I stated, my opinion is it's going to be a very, very small number of small volume surgeons are going to be included in those

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studies, if any, because you don't write up a paper if you've done 10. No one's going to get accepted.

Q BY MR. SNELL: Well, you wrote up a paper where you did 10 transobturator procedures?

A. Absolutely I did, and that was called a feasibility study. In properly counseled patients. I am not out there touting that that is the new gold standard. That's why we called it a feasibility study.

Q. Other than the Kuuva paper, what are you relying on for that statement that it would be a very, very small number?

A. Based upon my experience and attendance at national and international meetings, working at a tertiary care center, working on the journal articles from 15 different journals, that small volume surgeons don't write papers because there's nothing there to publish. So, therefore, my experience is, and I'll state unequivocally, very, very small percentage. If you want a number, 1 to 2 percent, if that. And they're not going to get published anywhere.

Q. Have you surveyed the literature for all the TVT retropubic device studies and done an

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analysis by which you segregated the investigators who had low to average surgical volume as compared to more than that?

A. I have reviewed the literature extensively. Can I quote to a certain specific paper? No. If you have one, show me, and I'll keep an open mind and modify my statement. But this is based upon experience. Again, national, international meetings. Editor -- or reviewer of 15 different journals. And I'm reading these papers constantly. And you're not seeing low-volume surgeons produce papers. The only one that comes close to it is Anger, et al., which demonstrated that low-volume surgeons had higher complication rates.

Q. Do you believe lower-volume surgeons with other stress incontinence surgeries, like the Burch or pubovaginal slings, have higher complication rates?

A. I would think that would be true. And those surgeons usually don't do those surgeries because they are more complicated surgeries to perform. It takes more talent to do. So most of those surgeons don't do it. That was the revolutionary aspect of TVT because it opened up

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minimal -- it opened up stress incontinence surgery to the common surgeon.

Q. Is the common surgeon unqualified in your opinion to do TVTs?

A. The common surgeon needs to -- no, the common surgeon -- let's be careful on the word "common." I'm saying the average, private practice surgeon, who is doing less than 15 or so a year, based upon the Kuuva study, et al., is going to be having a higher complication rate. Most of these studies also demonstrate in highly experienced hands.

So I'm saying as far as the common, the average surgeon out there, they are not going to have the expertise of the high-volume surgeons; hence, complications go up.

Q. Do you believe that surgeons in private practice have less surgical skills than surgeons in universities?

A. Absolutely not. It just depends upon their experience. There are some that I know in private practice who do very high volumes. It's not an issue of the specific individual. It's an issue of their volumes. And you know if you look at the Nilsson study, Nilsson is a five-year

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study. That was -- five-year study? Yeah. It's a five-year study.

See, they very clearly -- all surgeons involved were experienced urogynecologists well trained in TVT surgery. That's not going to be your average surgeon. That's are highly qualified people.

Q. How many average pelvic surgeons in the United States use TVT?

A. I can't answer that question. I don't know the -- a way of referencing it. We'd have to look at ethical sales and where they go to and the volumes that move off the shelf. That data would be available.

Q. Have you analyzed that data?

A. That data's been tried to get and can't.

Q. How many high-volume surgeons are there in the United States for TVT retropubic device as you define high volume?

A. There's going to be a certain number. But I don't know what that number would be. Around the nation there's going to be people that are going to be very good surgeons.

Q. Are residents -- do residents

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typically have higher complication rates than the, you know, professors or the surgeons who teach them?

A. It depends. If the resident is running solo and doing a case without any supervision, that possibly could be the case. However, if they have been well trained in a certain procedure and they're doing it solo and they've done more than anybody else -- they've done an acceptable number, their complications are going to be low. There's too many variables to be able to answer that question.

Q. If a surgeon is a -- strike that.

If a surgeon is more than an average surgeon, as you've stated, and he or she uses TVT retropubic device, based upon the data, you would agree then that the rate of complications are acceptable in his or her hands?

A. Number one, acceptable, no. Number two, it depends upon what -- how much follow-up they have. And it's true, a surgeon can put in the device and at one year that woman has not experienced any complications yet. But that device is going to stay in her the rest of her life. That's why I'm saying all these studies are

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insufficient.

Q. Have you analyzed the studies overall that show that the majority of complications do occur in the first 12 months?

MR. CARTMELL: Object to the form. I think it misstates the evidence in the studies.

A. Yeah. And it's also -- the complications they know of at that point. Because I can give you examples of bladder erosions that I've taken care of that I put in the sling that at 7 years they're fine. At year 8 there's an erosion, which we've examined. So we have to look at the life of the patient.

Q BY MR. SNELL: In the studies that report on TVT retropubic at five years duration or more, what is the rate of mesh exposure occurring after five years.

A. It's unknown.

Q. You mentioned the Wang paper. Let me just make sure I have it here. I think I do.

(Exhibit 19 marked.)

Q. BY MR. SNELL: Is this the Wang paper you referenced, Doctor, with regard to TVT?

A. Correct. 2004 publication, yes.

Q. And that paper says on the first page

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"Prolene tape seems unusually biocompatible when used as a suburethral sling"; correct?

It's all on the very first page.

A. I'm sorry. Where are you?

Q. Very first page. Right here.

A. That's what it states, yes.

Q. And so this paper by Wang is actually inconsistent with your belief that Prolene -- strike that.

Do you believe Prolene mesh is not biocompatible?

A. I do not believe it is biocompatible, no.

Q. In what percentage of patients is Prolene tape -- strike that.

In what percentage of patients is the Prolene mesh used in TVT for the treatment of incontinence not biocompatible?

A. That's impossible to know because there's been no good studies looking long-term at them.

Q. Well, in this paper, out of 700 women that you reference, the rate of exposure was 2.4 percent; correct?

MR. CARTMELL: Object to the form.

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A. Correct. During the time period of this study, of 7 -- I don't see what the follow-up is.

MR. CARTMELL: I think that misstates the evidence. The question assumes facts that are not in evidence.

A. The paper, at least in the abstract, does not state the follow-up time. But this paper states defective vaginal healing that became clinically significant was 2.4 percent during the study period. But, again, I'm trying to find the -- this is at 1 to 3 months. Defective healing from 1 to 3 months, it looks like. So it's a very short-term study.

Q BY MR. SNELL: Well, they actually looked at a longer time period than 3 months in this paper; right? It's just that the healing problems arose before three months; correct?

A. The acute healing problems arose during that time, yes.

Q. And so that means that 97.6 percent of the women did not have vaginal healing problems; right?

A. At the time the study was conducted.

Q. Fair enough.

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And you see there were four women what complained of dyspareunia? I'm right here in the Results section.

A. Five complained of pain and four complained of dyspareunia by themselves or their partner.

Q. And so four women complained of dyspareunia by themselves or their partner or partner discomfort; right?

A. Yes. So nine patients overall complained of pain.

Q. All right.

A. Four complained of dyspareunia.

Q. And as for dyspareunia, that rate is 0.57 percent; correct? This paper you point to.

A. A -- well, it's 4 out of 700 patients at that short-term follow-up. That's how many complained of dyspareunia.

Q. And does it sound about right that that rate is 0.57 percent.

A. I would have to do the math on it. I'll have to take your word for that.

Q. Well, 4 is certainly -- 4 women out of 700 is certainly less than 1 percent; right?

A. Well, if you look at this, 5 women

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complained of pain, 4 complained of dyspareunia, 5 complained of vaginal bleeding and irritated voiding. And so to break it down into specific little complications is disingenuous at best. But going to that, yeah, 4 out of 700 complained specifically of dyspareunia during this short period of time, short period of follow-up.

Q. And that's less than 1 percent; right?

A. It's whatever the math is. Again, I don't -- I can trust you on the math, I think.

Q. 5 out of 700's less than 1 percent; correct?

MR. CARTMELL: He's answered you. Asked and answered.

Q. BY MR. SNELL: I'm talking about the pain rate now. Not dyspareunia.

A. Pain? Well, pain -- if you want pain, it's going to be different. So it's going to be 9. Pain is roughly a 2 percent incidence of pain at that point in time.

Q. Where do you get 2 percent?

A. We have five women complained of pain. Four women complained of dyspareunia. Five women complained of vaginal bleeding and irritated voiding.

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Q. Doesn't say those five complained of pain.

A. No, they didn't. But they complained -- they complained of something else. So, again, what is always -- I'll let you have this, but as a doctor that takes care of patients who are crying in my office, you guys break down the complications. Yeah. So, yes. 9 patients in this series out of 700 complained of pain. The other ones weren't happy with vaginal bleeding, irritated voiding.

Q. That was five who weren't happy with vaginal bleeding or irritated voiding; correct?

A. Correct.

Q. And they ended up, 7 patients in this series that you point to required excision of the exposed suburethral part of the sling; is that correct?

A. That's correct.

Q. So that was an excision rate of only 1 percent in this entire cohort; right?

A. During the very limited follow-up duration of this study, that is the number they came up with.

Q. When you say limited follow-up

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duration, why do you say that?
A. What's going to happen in 5 years? 10 years? 20 years?
Q. How about this? Why don't we look a little bit further below that. You see the mean follow-up of 68.2 months?
A. Okay. What about 69 months -- I'm sorry.
Q. That's over five years, isn't it, Doctor?
A. And as I have mentioned over and over and over, this is an implantable medical device, as you mentioned. There are studies out there. Klinge, 15 years, degradation continues. This is a progressive process. I see these patients in my clinic that aren't being followed by anybody. So I'm saying 5 years, that's a step in the right direction. But if a woman lives 30 years beyond that, what's going to happen in that time frame? Our data suggests it's going to get worse.
MR. SNELL: Move to strike.
Q. BY MR. SNELL: In this paper you point to -- you pointed me to, at over 5 years follow-up, there was only 1 percent rate of mesh excision to treat the exposure; right?

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A. That is what the study stated at five years, yes.
Q. So that means at a mean follow-up greater than 5 years, 99 percent of the women in this entire large cohort didn't need a mesh excision procedure; correct?
A. The key is yet.
Q. And there are other studies that report --
MR. CARTMELL: Just for the record, I want it to be clear, because I think it's unfair to the witness that you've been representing that there was a small number of erosions. And I think there were 17 erosions in the cohort. And I want the record to be clear for that.
MR. SNELL: I think -- the study says what it says, so I can't --
MR. CARTMELL: Yeah, but you're just kind of trying to trick him, you know, because you --
MR. SNELL: I'm not tricking him. He pointed to this study, Tom. He knows this study. Don't try to tell me I'm tricking a witness about a paper he told me -- he's pointing me to.
MR. CARTMELL: So don't say --

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MR. SNELL: You're not testifying, Tom, please.
MR. CARTMELL: -- there's 7 erosions when there's 17 erosions. In fairness.
MR. SNELL: You know what. You're totally off base.
MR. CARTMELL: I am?
MR. SNELL: Yes.
MR. CARTMELL: Tell me how.
MR. SNELL: On your time I was asking him about erosions that needed surgical -- where's the paper? We just went through this, didn't we, Doctor.
MR. CARTMELL: 17 erosions. 17 erosions, it says right here.
MR. SNELL: Tom, you're being nonsensical. I asked him about the ones that required excision.
MR. CARTMELL: No, you didn't. You said erosions in general, and the record will reflect that.
Q. BY MR. SNELL: Sir, don't you remember me asking you about 7 of those patients required excision of the exposed suburethral part of the sling? Didn't I ask you about that?

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A. You asked me a question. I can't remember the specific details of it.
Q BY MR. SNELL: But it says seven required excision of the exposed suburethral part of the sling; right?
A. That's what that says there, and the other part says 17 out of 100 had defective vaginal healing.
Q. And it gives the measurement, CA 1 times 0.5 centimeters; correct?
MR. CARTMELL: Okay. Now, it's all on the record. Now it's fair.
MR. SNELL: It was fair before. He cited to the document. He knows the study.
(Exhibit 20 marked.)
Q BY MR. SNELL: Giving you one of the publications by Klinge, Alloplastic Implants for the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse.
You see this?
A. Yes, I do.
Q. Whereas you cited to Klinge about hernia and other papers, you didn't cite to his discussion of the TVT mesh; did you?
A. I don't recall that specifically.

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Q. Look for where Klinge was writing about meshes in stress urinary incontinence. You there?
A. Yes. I mean, I'm sorry. I'm at the Meshes and Stress Urinary Incontinence. I'm there now.
Q. All right. And you saw Dr. Klinge was one of the authors of this section; right?
A. Correct.
Q. And it says, "At present the gold standard in SUI surgery is the suburethral sling using either the tension-free vaginal tape (TVT) or the transobturator tape (TOT) technique"; correct?
A. That's what he states, yes.
Q. And do you disagree with Dr. Klinge?
A. I disagree.
Q. It said, the initial concern that the meshes used might lead to high rates of erosions, did not hold true when macroporous polypropylene was used; correct?
A. That's what it states, yes.
Q. And here when Dr. Klinge is talking about macroporous polypropylene in the context of stress urinary incontinence, he's talking about

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the mesh in TVT; correct?
MR. CARTMELL: Object to the form.
A. No. He doesn't state which he's talking -- referring to. The sentence prior, it says TVT or transobturator tape. There's a lot of different ones out there. And then he says, "The initial concern that meshes." He does not say TVT. So all he's saying is meshes.
Q BY MR. SNELL: Well, you see below that, right, where he talks about -- he follows up on his point.
He says, "There was a zero percent exposure rate using the classical TVT (Type 1 macroporous monofilament polypropylene) mesh in the same trial"; correct?
A. Well, that's in the second -- in the next paragraph down. I'm talking about the sentence you showed me. Initial concern that meshes. So it doesn't say TVT. We can agree it says meshes, and I'll agree that's what it states, but he doesn't say TVT.
Q. We can agree that he says the classical TVT (type 1 macroporous monofilament polypropylene) mesh; right?
A. That's what he's saying when he's

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referencing to the Meschia study.
Q. And you know that that's a study that looks at the Ethicon TVT retropubic device?
A. I'd have to look back at the study. I don't remember the study.
Q. Okay. So at least in the context of the intended use to treat stress urinary incontinence with regard to the TVT device, he reports that tape is a type 1 macroporous tape?
A. That's what he reports in 2010.
Q. Right.
A. Which then reflects data from 2008. And that's what he states.
I disagree with it. Be interesting to what he says now.
Q. Now that he's been paid hundreds of thousands of dollars by the plaintiffs' lawyers in the mesh litigation?
MR. CARTMELL: Object to the form. It's argumentative. Be distracting.
A. If you want to go on the record that he's being biased.
Q BY MR. SNELL: Do you know how many royalties he -- Dr. Klinge received on Vypro?
A. I'm not familiar with that number

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because I'm doing involvement of TVT case, not Vypro.
Q. Do you know how many royalties Dr. Klinge has received for ULTRAPRO?
A. The same answer as before, because I know what data I've been provided on TVT. I have not been provided confidential data on Vypro or the other ones.
Q. And you don't disagree that when Amid type 3 mesh, used for intravaginal slingplasty, the vaginal erosion rate was 9 percent, and the rate was 0 percent with TVT?
MR. CARTMELL: Object to the form.
A. I agree with the first part. I don't agree with the second part.
The Amid type 3 like the ObTape, which I'm very familiar with, had an unacceptably significant complication rate with it.
Q BY MR. SNELL: And you didn't cite to this writing by Klinge in your expert report; did you?
A. I cited Klinge multiple times. I don't know if this specific -- this is a book chapter. I quoted this one. Book chapters I tend not to quote.

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Q. Well, this is one place in the medical literature where Dr. Klinge discussed his views on what type of mesh TVT mesh was in the application of treating stress urinary incontinence and whether or not it was the gold standard.

Have you seen that published anywhere else?

MR. CARTMELL: Objection.

Q BY MR. SNELL: By Dr. Klinge.

MR. CARTMELL: Objection. And move to strike this statement of counsel.

A. And I agree with you completely, and that should tell you something about Klinge's expertise, as far as a stress urinary incontinence surgeon, which he is not. He's a mesh expert. But he's not a transvaginal surgeon. He's never been involved in one of these cases. So you search around and find one reference where he's quoting something in the book, okay, that's what it is.

Q BY MR. SNELL: He doesn't just quote something in a book. He's actually citing data, randomized trial data on TVT versus an alternative mesh; doesn't he?

A. I'm saying he is not a surgeon. He's

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not providing expertise as a pelvic surgeon like I am. He's a mesh expert, a very good one, but he is not a pelvic surgeon.

Q. Do you know how many royalties Dr. Klinge gets with regard to his work with the German DynaMesh mesh?

A. I have not heard a number, no.

Q. You know he does get money from that mesh; right?

A. I just said I don't know. I don't know. I'm not a faithful apostle of Dr. Klinge. I don't know what he does.

Q. Do you acknowledge he's got a conflict --

MR. CARTMELL: All you got to do is answer do you know or not.

A. I do not know.

Q BY MR. SNELL: You know that he has a conflict of interest when it comes to DynaMesh; don't you?

MR. CARTMELL: What it comes to what?

MR. SNELL: DynaMesh, D-y-n-a-M-e-s-h. It's a mesh that's not even available here in the United States.

MR. CARTMELL: So then why would he

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know?

MR. SNELL: So the question is would you -- well, I take it he's read Dr. Klinge's writings. He's seen Dr. Klinge's statements.

MR. CARTMELL: What writings are you asking him about? If you have writings about DynaMesh that you want to ask him about, put them in front of him. Why all the questions about studies and things that you don't even let him look at.

MR. SNELL: He can look at anything he wants.

MR. CARTMELL: Then put it in front of him.

MR. SNELL: It's not my job to put it in front of him. It's the job of your witness to bring his file. Secondly, he cites to Klinge about 100 times in the report, and not once does he acknowledge any of this.

MR. CARTMELL: If you're going to ask him about a study specifically on it that's on his reliance list, then bring it with you and ask him questions and let him look at it so it can be fair. How about that? How about that?

MR. SNELL: He could bring his own

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file. How about that? That was asked and requested of him, Tom.

MR. CARTMELL: You have everything he has reviewed.

MR. SNELL: Tom, my experts bring their file to the depositions.

MR. CARTMELL: Wrong.

MR. SNELL: You remember when you deposed Denise Selzer she showed up with nine boxes of stuff.

MR. CARTMELL: Denise Selzer did.

MR. SNELL: Christina Pramudji showed up with boxes and boxes and boxes of stuff.

MR. CARTMELL: Not when I deposed her.

MR. SNELL: Get for real. You know she did. Crazy.

A. But to address your question, as far as conflict of interest, if he truly does have conflict of interest and bias, then based upon this here he's coming out in support of TVT. So I see a fault in your logic.

Q BY MR. SNELL: I don't have a logic. I'm asking you a question.

A. Well, I know you don't have a logic and that's what I've been pointing out.

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Q. My question is: You were aware of these writings by Klinge with regard to TVT and that mesh and the specific intended use of stress urinary incontinence before you wrote your report; right?
A. I'm aware of this reference.
Q. Yes. You were --
A. The one that I'm holding, Exhibit 20. I don't recall if I've ever been aware of this.
Q. The plaintiffs' lawyers never gave that to you?
A. I don't recall if they have. I have thousands of pages they've sent me. It may have been in there somewhere. I have not seen this. Again, if he were a pelvic surgeon, I would be putting weight into his comments on gold standard and things. But all he's doing is parroting what he's read somewhere else. So, again, it is what it is.
Q. Can you point me to any other publications by Klinge where he assesses the TVT retropubic device in the application of stress incontinence and discusses the clinical studies on that device like he did in that paper I just showed you, Exhibit 20?

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MR. CARTMELL: Object to the form. It misstates the actual paper.
A. He has studied extensively hernia meshes. TVT is a hernia mesh. But to put all the dots together as you very narrowed it down to, the answer to that is no, not that I am aware of.
Q BY MR. SNELL: My focus is the intended application of the treatment of stress incontinence and those studies alone.
You haven't seen that paper or those papers?
A. As you word it there, I have not seen that. The intended application of the TVT mesh was actually for hernias. Not for female stress incontinence. So, again, he has studied the intended purpose of that mesh. He has not studied it when it's been put into the vagina.
Q. For the TVT device, that's what I'm referring to for its intended -- you've acknowledged that the TVT retropubic device is intended to treat stress urinary incontinence; right?
A. The device is, but the mesh intended use was for hernias, which was then extended to the application of stress urinary incontinence.

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So, again, I'm agreeing with you and disagreeing with you at the same time. Not to be difficult.
MR. SNELL: Okay. Let's take a quick break so I can get organized.
(Recessed from 3:05 p.m. to 3:07 p.m.)
Q BY MR. SNELL: I want to ask you about your opinions about the mechanical cut of the TVT retropubic device.
You've mechanically cut mesh before?
A. Just the sacrocolpopexy mesh. Not sling mesh.
Q. And did it ever concern you when you were cutting sacrocolpopexy mesh mechanically?
A. It didn't. And now it does.
Q. Do you still cut sacrocolpopexy mesh?
A. No. We modified -- well, we're in the process of modifying it to using Restoril, which will not hopefully have that problem. It's already hemmed. And that is a concern of mine which I now counsel my patients on.
Q. And is it fair to say that you believe the laser cut TVT mesh is defective?
A. I think it's treated one -- to specifically answer your question, yes.

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Q. I didn't see in your expert report where you cite to any TVT studies with regard to clinical complications occurring at a statistically higher rate with mechanical cut TVT mesh as compared to laser cut TVT mesh.
Is that a fair summary of your report?
A. You are correct. I have not heard of a study with that. However, I'm basing that on Nilsson's comment of a four-time -- four times increased risk of vaginal extrusion with a laser cut.
Q. What comment is this by Nilsson? I'm sorry.
A. That was in one of the documents I read. I don't know where I read it, but it's in the document.
Q. What methodology did you use to select that one quote by Nilsson?
A. Because he is arguably one of the world's experts on it. And so I value his opinion on this.
Q. Do you also value his statement in the company documents that he will not use laser cut mesh; that he only uses mechanical cut mesh?
A. Absolutely. That's supporting what I

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just said.
Q. So you're aware that Nilsson only -- in the company documents, reports that he will only use mechanical cut mesh?
A. That's -- I don't know what his recent statements are, but that the document that I read, which that source can be found, he said he would not use the laser cut because of the four times increased risk of vaginal extrusion, and he would only use the mechanical. Then I read the other individuals stating the exact opposite. So I get conflicting evidence. I have not seen, to the best of my knowledge and it may be out there somewhere, a study, comparative, randomized clinical study of the two. I've not seen it.
Q. Are you aware of any TVT retropubic clinical data that reports that there's a higher rate of complications with mechanically cut mesh compared to laser cut mesh?
A. I don't think overall there's going to be a higher risk from one or the other. They're both bad and both have their set of complications. So you're trading one set of problems for another set of problems.
Q. What studies are you specifically

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relying upon for your opinion with regard to the mechanical cut TVT retropubic mesh, if any?
A. Well, that's what I'm talking about. The methodology that I have used with this, concerning specifically mechanically cut, is obviously the internal documentation, with complaints coming in about the fraying, roping, particle loss, the inflammation. Reviewing of the papers talking about various different complications. My clinical experience dealing with patients. Last week alone, there's one patient. Week before that, three, which were all TVT patients. Where that I see this mechanically cut mesh. Then my discussion with colleagues at international and national meetings. So all that is going into it.
Q. You said the papers. You reference papers. Are you talking about Ethicon documents?
A. Correct. Well, I mean the medical literature, too.
Q. That's what I'm asking. What medical literature on TVT reports complications attributed -- attributed to the mechanical cut nature of the mesh?
A. The defect in -- and every paper I've

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ever read on TVT. If you have something different, then I'll keep an open mind. I have yet to see any paper describe we're using mechanically cut or we're using laser cut. So I can't base it upon that.
Q. Okay. So when I was asking about what papers you were talking about, I thought you were talking about Ethicon company documents and not medical literature.
A. No. That was one of them. The internal documentation -- I'll just be clear.
As I stated in the previous answer, internal Ethicon documentations, medical literature, the emails back and forth, and then my clinical experience. That's how I came by it.
I am not here today to say that laser cut is better or worse. They're both bad in my opinion.
Q. So with regard to your selection of which company documents to put in your expert report on this mechanical cut issue, what was your methodology in selecting those particular company documents?
A. My methodology of what I reviewed is very simple. Every document that I was provided

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with internal documentation from Ethicon I reviewed.
Q. So you were provided those by the plaintiffs' lawyers?
A. Correct.
Q. My question to you is this: Let's focus on your methodology for which ones you decided to cite in your expert report as support for your points.
What was the methodology in that?
A. You have to -- you have to analyze --
MR. CARTMELL: Well, just for clarification, you mean because they're all cited in his report.
MR. SNELL: No, they're not.
MR. CARTMELL: There's a reliance list.
MR. SNELL: There's a reliance list, but he cited certain things.
MR. CARTMELL: Okay. So you're distinguishing between what's in a footnote versus what's in the reliance list that's attached.
MR. SNELL: Of course, because, I'm sure, everything in the reliance list doesn't support the things he says.

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MR. CARTMELL: Well, everything on his reliance list is information he used in forming his opinions and relies on.
MR. SNELL: You're speaking -- you're doing a speaking objection.
MR. CARTMELL: Well, I'm responding to your statement you just made. You're talking about only the citations in the report.
MR. SNELL: Yes. That is my question. That is my question. Do I need to repose it again so we have a clear record?
THE DEPONENT: No.
Q BY MR. SNELL: Why don't we just do it again.
A. That's fine.
Q. Otherwise there's just going to be four pages of gap.
What specific methodology, did you use in determining what Ethicon documents you would cite to in support of your opinions where you listed them in the footnotes?
A. Okay. I have to look at the body of knowledge out there on medical literature, my clinical experience and what I see day to day, correlating that with what was known and discussed

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in the Ethicon documents, whether it be from their scientists, from their medical experts, from their clinicians calling in, correlating that and does it all fit. Everything has to fit logically, okay, and that was what was included in this.
Q. So, for example, did you see company documents that indicated that the majority of surgeons in the United States actually prefer mechanical cut mesh as opposed to laser cut?
A. I've seen that, yes. Well, I'm sorry. Let me take that -- strike that.
I do remember seeing and reading that certain physicians would not change to the laser cut. I can't say that the majority did. I also see that certain surgeons would not use the mechanical one because of the fraying and the particle loss. So I don't know the percentage of who uses what.
Q. So you were not provided documents that state that the majority of surgeons in the United States who use TVT prefer the mechanical cut mesh as opposed to laser cut; fair?
A. I may have been provided that. I don't recall that specific document.
Q. If that document existed, what would

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be your methodology for excluding it or not referencing it in your report?
MR. CARTMELL: It was on his reliance list.
A. Yeah. To a certain extent, surgeon preference is important, and then also not important. So certain surgeons choose to do one product over the another. The fact that 51 percent like the mechanical cut and 49 don't, it doesn't matter to me. Again, we're not talking about one product being great and the other one being horrible. They're both bad. So to me it's immaterial.
Q BY MR. SNELL: Did you assess or look at the reported rates of sales of mechanical cut versus laser cut in the United States?
A. Well, from my angle as a doctor, the needs of the patient come first. And sales are not an issue that I'm going to be concerned about.
Q. So the answer is, no, you didn't look at that?
A. The answer is what I just stated.
Q. Sir, my question is very simple, which is: Did you look at it?
I understand you want to give me a

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speech on things, but if you could just give me a yes or no answer, then I can move on. If you say no, then I'm going to move on.
A. Well, no, because my speech, as you did, is based upon my taking care of patients who are crying in my office from pain. So I don't dismiss it as a speech. But medical marketing sales are not something that's going to factor into my decision.
Q. I believe earlier you were talking about complications, and I think it may have been around mesh exposures, where you said there would be numerous different factors like patient factors, surgeon factors, the mesh.
Do you recall that?
A. Yeah. Concerning vaginal exposure. I don't recall if I mentioned patient factors involved in it, but, I mean, maybe I did. I don't -- I'd have to see exactly what I said.
Q. I wrote it down.
A. It's a multifactorial problem that leads to that complication.
Q. What are the patient factors involved?
A. Well, that's difficult because it's -- I don't know of anyone ever studying to show

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consistently a patient factor being involved in the exposures. Smoking, I'm not aware of. Obesity, I'm unaware of. Vaginal atrophy -- I don't know of patient factors that can be consistently proven to be a factor in vaginal exposure.

Q. You are -- vaginal atrophy is a condition that women have that can progress or get worse as they get older in their postmenopausal years if not supplemented with some type of estrogen; fair?

A. There's the possibility of that, yes. Not in all cases.

Q. But is that a common finding in women who are postmenopausal that there is some degree of vaginal atrophy?

A. It's not uncommon, let's put it that way. So, yeah, it does occur.

Q. Is there a recognized weight classification specific to stress urinary incontinence slings that has been endorsed and put out by any of the pertinent professional medical societies?

A. Pertaining to what? I guess I don't understand your question. That they should or

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should not get a TVT?

Q. No, no. For the intended use of stress urinary incontinence.

Is there a recognized weight classification system for slings?

A. Well, no. The BMI is the standard what is used. And but there's not, as it pertains specifically to SUI treatments.

Q. I think you and I -- we weren't on the same wavelength.

For the weight of the mesh --

A. Oh, okay.

Q. -- and the intended use of treating stress urinary incontinence, is there a recognized weight classification system that's endorsed by the professional societies?

A. No. As far as -- even in industry, industry and surgical societies, there is -- as far as I know, there is no specific classification. I think they have heavy weight -- you know, Cobb and others taught about heavy weight. So there would be that. And above certain -- or below certain numbers would become medium weight and lightweight. I don't know if I can -- I can't quote a society that has this

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standard thing that's out there. Same thing goes for pore size, too.

Q. And my focus is on the intended use with the stress incontinence device and the application to treat stress incontinence.

A. Closest thing I think would have to be a Clave study, breaking it down to the various weights, I think, if I'm answering your question correctly. But that's not as it pertains specifically to SUI.

Q. Right. That's what I'm looking for is SUI.

A. I am not aware of that specific narrow application.

Q. For SUI, the slings are typically around 1 centimeter wide.

A. 1 to 1.5, probably.

Q. Ethicon's TVT is reported to be about 1.1 centimeters; correct?

A. As it comes out of the box, which is an important distinction.

Q. Yeah.

A. But, yeah, they're all about that width.

Q. Is it a fair statement that all of the

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mesh slings, synthetic mesh slings that are used to treat stress urinary incontinence have a weight of more than 60 grams per meter squared?

MR. CARTMELL: Object to the form. May call for speculation.

Answer if you know.

A. Yeah. All I can speak to is Aris, which I know is at 70. TVT at 105. I don't know that the other products.

Q BY MR. SNELL: You read Moalli's paper on the biomechanical evaluation of slings?

A. I read it at one point in time. Not recently.

Q. It has a table in there where it has the reported weights of the different slings.

A. Okay.

Q. Is that a paper you're relying on, the Moalli paper?

A. That's in my reliance list. But I'm just saying I haven't read it recently. You're referring to the 2007 paper?

Q. Give me the title and I'll tell you.

A. Tensile Properties of Five Commonly Used Mid-Urethral Slings Relative to the TVT, by Moalli, et al., June of 2007. Published in 2008.

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Excuse me.
Q. That's it. Yeah. Is that a paper you're relying on?
A. Yes.
Q. Are there any studies in the stress incontinence application with the use of TVT that show that a lighter weight mesh is either more efficacious -- strike that.
Let me just say is more efficacious than the TVT?
A. Can you rephrase the question, because as I'm reading it. I can't quite understand.
Q. Absolutely. Yeah.
Are there any clinical studies evaluating efficacy in women with stress urinary incontinence that show that a lighter weight mesh works better than the TVT retropubic device?
MR. CARTMELL: Object to the form.
A. No, I don't think the weight of the mesh --
MR. CARTMELL: Can I -- can I get this? Can we take a break.
MR. SNELL: Yeah. An opportune time.
(Recessed from 3:31 p.m. to 3:32 p.m.)

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MR. SNELL: Can you read back the question?
(The reporter read the record as requested.)
A. As is worded there, I'm not aware of it. I mean, Cobb and internal Ethicon documents talk about lighter weight being better, fewer complications, sort of things. But as you specifically narrow it down to TVT, there is not that study.
Q BY MR. SNELL: And my question -- the initial question was on efficacy.
A. No. As far as I know.
Q. Okay.
A. There is nothing out there, as far as the lightweights.
The move was in hernias and pelvic organ prolapse to go to lighter weight because of the complications, but that was decided against with TVT.
Q. And so my question is I want to get into -- ask you about the complications.
Are you aware of any clinical studies showing a lower rate of complications in women who receive a lighter weight mesh for the intended use

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of treating stress urinary incontinence?
A. No. I've only seen it in pelvic organ prolapse data and in meshes. Meshes for hernia repairs, but it was not extrapolated, even though Ethicon knew about it, into stress urinary incontinence.
Q. All right. And you're not testifying that a lighter weight mesh would have worked better than the TVT mesh in the TVT retropubic application to treat stress urinary incontinence; are you?
MR. CARTMELL: Are you talking about efficacy only?
MR. SNELL: I can go with efficacy first.
A. There is no data out there on it. That would be an important thing to do before a launch is to study that to determine efficacy prior to widespread use.
Q BY MR. SNELL: You would agree it's a benefit for the TVT retropubic device that they do have studies of 5 years, 10 years, or more duration in the literature?
MR. CARTMELL: Object to the form.
A. Yes, as we mentioned concerning

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efficacy, but not safety.
Q BY MR. SNELL: Well, there's --
A. The lighter meshes, the larger pore, lighter weight meshes are for complications. Not for efficacy.
Q. And I understand you say that with regard to prolapse and hernia. My question to you is: With regard to complications, is it your opinion that a lighter weight mesh was used in the application of TVT for the treatment of stress incontinence, cut to 1.1 centimeters, that there would be a lower complication rate?
A. There's the theoretical possibility of that. However, my ultimate opinion is no meshes should be placed transvaginally.
Q. Fair enough.
You mentioned the Clave study. That was not a study that reported on the use of the TVT retropubic device in women who had been treated for stress urinary incontinence; correct?
A. Correct. That was, as I recall, for pelvic organ prolapse.
Q. Is this the Clave 2010 paper?
A. Correct.
Q. Okay.

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(Exhibit 21 marked.)
Q BY MR. SNELL: I've given you Exhibit 21. This is the paper we were referencing by Clave; correct?
A. Correct.
Q. Okay. This is the paper where they start out with 100 explants and they only subjected 84 of them to scanning electron microscopy; correct?
A. Well, there were 100 explants, and I'd have to look through how many got evaluated with SEM. I don't recall the exact number. If you say it's 82, I'm okay with that.
Q. 84.
A. 84.
Q. I wouldn't misrepresent to you. Right there.
A. Okay. I got it.
Q. You go it?
A. Um-hum. Thank you.
Q. Under SEM analysis, it found that less than half of the implants had this surface cracking; correct?
A. It's an extremely high number, yes.
Q. There were 35 out of 84?

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A. Yeah. That's -- that's a worrisome number to me. I mean, it's 35 out of 80 women are having this degradation going on.
Q. And besides just looking at the pictures on the SEM and seeing the cracking and saying that must be degradation, when they actually did tests to analyze and see if it was degradation, those testings did not show it was degradation; correct?
A. You'd have to show me where you're referring to.
Q. How about --
A. Because to me, degradation is cracking, brittle --
Q. 266.
A. 266?
Q. 266. You know that after doing the scanning electron microscopy, they subjected them to FTIR, DSC analyses; correct?
A. Correct.
Q. And if you look at the bottom of page 266, they reported that several hypotheses concerning the degradation of the PP are described below. None of these, particularly indirect oxidation, could be confirmed in this study.

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I read that correctly; didn't I?
A. I didn't see where you're reading.
Q BY MR. SNELL: Right here.
A. 266 or 267?
Q. 266 at the bottom right.
A. Oh, yes. I see it now. Yes. I'm sorry.
Q. So when they try to do the other testings, the FTIR, the DSCs, they did not confirm degradation; correct?
MR. CARTMELL: Object to the form. Misstates the statement.
A. Again, I'd have to see where you're reading. I don't know where this is coming from.
Q BY MR. SNELL: This is a question to you based on this study.
A. Again, I'd have to -- it's been a while since I've gone over this paper. So I'd have to find all the nuances you're discussing. I mean, they describe degradation. They describe cracking, and to me that's degradation.
But the exact etiology of it, I don't recall from the study what they came up with.
Q. Well, when you see this cracking, that could be polypropylene or something other than

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polypropylene; correct?
MR. CARTMELL: Object to the form.
A. Well, all I can quote, as far as my experience, obviously I have these papers which I reviewed, but I can only correlate that macroscopically to my surgical experience. When I take out these meshes, which I did, it happened to be a TVT-Secur last week. Where you hold it, it's brittle, it cracks, it breaks, it's sharp; it pokes the finger. Okay. To me that is degradation.
Now, on the microscopic level, you know, I don't know what exactly they call and what specific words they use to describe that process.
Q BY MR. SNELL: They didn't say it was brittle and broke and cracked in your fingers in Clave; correct?
A. No, they didn't say that. I'm saying that's what me and my daily experience, including just last week -- that's what I feel, and that's what I'm calling degradation of the product.
Q. Clave and them show pictures of scanning electron microscopy with surface cracking?
A. Yes. But none of these are TVT, you

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said. So this is a very important study. Seems like they're raising red flags.

Next step is Ethicon needs to study it with their specific product.

Q. And in Clave the explants have been explanted because of reported complications; correct?

A. I believe so, yes.

Q. There was no control group in this study of explants for which there was no complication reported; correct?

A. Well, yeah, the complication was a manifestation of underlying pathology. So, no, you don't have a control because you're not going to go operate on women who do not have a complication yet.

Q. And so the authors were unable to state whether or not this amount and this type of surface cracking is something that occurs in non-explanted meshes?

A. I mean, you're really narrowing down the focus of this. Again, it's not a TVT product, but they were not able to say -- I guess, I'm not really following your question. I'm sorry.

Q. What I was getting at is on page 269,

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they say, "For obvious ethical reasons this study did not provide the opportunity to analyze vaginal implants from non-pathological situations. Therefore, prediction of normal in vivo material aging and the range of consequences in the clinical state beyond the observed samples is not possible."

A. That is correct.

Q. Okay. Can you point to any clinical studies, any studies on the TVT device to treat women that showed degradation of that TVT mesh?

And if you're looking at your report, just tell me what page so I can --

A. Page 13.

Q. Give me a second. Okay.

A. Specifically if you limit it to just TVT, obviously I quote multiple different studies looking at polypropylene and the foreign body response, the inflammatory response, the degradation, you have Mary, et al., Costello, Clave, Wood. But on page 15 at the very top, the first full sentence says, "In 2015 seven implants." And that is -- if you look down at reference 11, it's a Russian name, I think. T-z-a-r-t-z-e-v-a. In-depth nano-investigation of

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vaginal mesh and tape fibers explants in women, okay. And that included TVT. They were removed four to seven years after, and it demonstrated degradation on SEM, and surface cracks, which corresponds to my clinical experience.

Q. In these seven explants, was there any oxidation found of the TVT mesh?

A. Oxidation is the process by which you get degradation. So in order to study for oxidation, you have to do some pretty sophisticated chemical studies on the microscopic level as far as what macrophages are doing. I don't know -- I'm not an expert on how exactly that would be accomplished. But if there's degradation, I know there's been an inflammatory response, which inflammatory response causes oxidation, is one of the main reasons with peroxides, hypochloric acid, et cetera.

Q. Has the reported degradation in these seven explants been confirmed in any standardized test, such as chemical analyses?

A. I'm unaware. I have to go back to the study and see what they've done from that. From my angle as a surgeon, I would want the company then to go back and look at some of this stuff for

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me.

Q. Are there any studies that you're aware of on the TVT device that correlate and show that a particular complication was caused by degradation?

A. Well, no. Degradation is part of the cascade of events. You have an implantation of a product that causes a foreign body response and inflammatory response, which then the immune system comes in with the various different dumping of various different product to try and to eliminate the foreign body, infection, and then degradation occurs.

So you're not going to find something where it's just degradation. It's a cascade of events.

Q. Is there any clinical literature that shows any complications are caused by degradation?

A. Well, I would say every study that there's a vaginal erosion or extrusion is evidence of degradation. Yeah, every time that I do an exam on a patient and find this brittle, cracking, hard mesh that is evidence of degradation.

Q. Are there any studies that report degradation played any kind of role in a vaginal

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erosion or extrusion following a TVT?
A. Well, yeah, this T-z-a-r-t-z-e-v-a on page 15. There are seven explants, including TVT, that were removed after implantation. Okay. So some sort of complication. And they found degradation there.
(Exhibit 22 marked.)
MR. CARTMELL: Just so you know, Doctor, for the record, a lot of times people call it the Zimmern study. It's easier to the pronounce.
THE DEPONENT: Yeah. Phillippe at UT Southwestern.
Q BY MR. SNELL: This is the paper you were referencing?
A. Correct. It's an abstract.
Q. It's T-z-a-r-t-z-e-v-a.
A. Yeah. It's Zimmern. Phillippe Zimmern at Utah Southwestern's paper.
Q. And this wasn't seven TVT devices as you put in your report; was it?
A. No. I said including the TVT. So not all were TVT.
Q. Right. In fact, how many of these were TVTs?

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A. I don't know if it actually says. Seven explants. But I don't think they break it down into what -- which one has what.
Q. Well, they had a Gynemesh; correct?
A. Correct.
Q. And that's not a TVT retropubic device; correct?
A. No. It's an Ethicon product.
Q. Then they had a TVT; correct?
A. Yes.
Q. They identify one TVT in this study you cite; right?
MR. CARTMELL: Object to the form. Misstates the paper.
A. Again, I'd have to see where it is.
Q BY MR. SNELL: Well, you cite to it, Doctor. So I'm telling you, they cite to one TVT in this study; right?
MR. CARTMELL: That's not what it says. It misstates the paper.
A. That's not what it -- it says seven explants were studied covering a range of currently MT devices, Gynemesh, TVT, TOT, Sparc, and mini sling.
Q BY MR. SNELL: So that's five

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different devices; correct?
A. That's right. That's five different devices. So TVT could be three of them. What I'm saying is this particular abstract does not break it down into which one is which.
Q. And you don't have a clue then as to whether one was a TVT or two or three; correct?
A. As I've stated, the abstract does not state that.
Q. And this abstract doesn't state what complications, if any, occurred with the TVT; correct?
A. No. It states they were explanted for some reason.
Q. And you note in this study they looked for peaks of oxidation, and they didn't find any; right?
A. Okay. You know, they did or didn't. Immaterial to me because it shows degradation. Degradation can occur because of multiple different reasons, but they didn't find it on this particular study.
Q. And they didn't try to say the clinical effect, if any, of a 7-nanometer degree of surface cracking; correct?

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A. Well, no, you have to extrapolate. There was a complication on all seven of these. They had degradation. They had cracking. Something went wrong. Was it infection? Was it pain? Extrusion? Contraction? Dyspareunia. I don't know. I'm just going -- they don't state in this paper, in this abstract.
Q. Do you believe that there are any clinically significant complications that occur because of degradation?
A. Yes.
Q. And where do you identify them in your report? I'm sorry.
A. That is in the section on Degradation, beginning on page 13 through top of 16.
Q. So what specific complications, if any, arise because of degradation?
A. Well, that's what we've talked about multiple times here. Degradation is one of the steps of the problems. It starts with implantation of a foreign body in a contaminated environment that creates inflammation, foreign body response. Macrophages come in. They dump their hydrogen peroxide, hypochloric acid. The product breaks down. It creates more of an

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inflammatory process. And it's a vicious cycle, which leads to then scarring, contraction, scar plate, dyspareunia, pelvic pain, urethral erosion, bladder erosion.

So degradation is one of the steps of this cascade.

Q. Are you aware of any reliable scientific studies that show the degree to which degradation causes any of these complications you just identified as compared to surgical technique, patient factors or any other causal elements?

A. See, that's exactly what I've been trying to state this entire time. The whole device, as marketed, is bad because surgeons play a role. The patient may or may not. I think that's questionable. We talked about that already. I can't find an identifiable source there. But then you have a bad product put in.

So the whole thing is bad. It's multifactorial reasons why certain number of these patients have devastating complications.

Q. If a patient has a mesh exposure, do you assume that degradation was a cause?

A. Depends partly on when it occurred. However, I believe Clave said it was independent

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of time of implantation that they found their degradation. The longer it's in, intuitively and based upon the data and based upon like Klosterhalfen says 15 years, degradation contraction continue, that the longer it's in, there's going to be more problems with it.

Q. Well, Clave, they didn't even find surface cracking in half of the explants.

A. But they found it in half. So tell a patient, great, half of you aren't going to have it at that point in time, but the other half are.

Q. Maybe we're not communicating.

We've already gone through Clave, and it didn't show degradation or surface cracking in more than half of the implants.

A. It was like 55 percent or something like that, or in that ballpark.

Q. Right. Right.

So in those 55 percent, right, some of those patients would have had exposures; right?

A. Possibly. I don't believe the article states it.

Q. Yet they didn't see surface cracking; right?

A. So that means something else was going

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on.

Q. So that's what I'm asking you then, okay?

How do you know which exposures degradation played a role in, when in Clave they didn't even see degradation, except in 45 percent of them?

A. Okay. Then -- I mean --

Q. That's a scientific question I'm getting at.

A. Well, yes and no with that. So 45 percent of the patients, based on Clave, had degradation and complications. That means the other 55 had other factors, surgical, implantation technique, roping, curling, whatever, to cause complications. For myself, as a surgeon who takes care of these patients, I ultimately don't care what causes the problem. I've got a problem I've got to deal with.

So if we want to base it upon Clave, 45 percent of these complications could have occurred due to degradation. It's 45 percent of patients who have been damaged due to degradation of the product.

Q. Is that an opinion you hold

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45 percent --

A. No.

Q. -- of exposures occur because of degradation?

A. No, I don't. We're saying based upon the Clave study. I have yet to see -- and this would be a very good study to be done, and it should be done by Ethicon, if there's a concern and they want to take care of patients and prevent women from being damaged of studying these things.

Q. But I'm here to learn your opinion; right.

What percent of the women who have an exposure is that caused by degradation?

A. I guess --

Q. If you can't say or you don't know, tell me that. But if you have a number, then I want to know the methodology by which you come to -- come to that number.

A. If I have a patient who is seeing me two or three days after a mesh sling with exposure, that's not due to degradation, okay.

Q. That's her wound hasn't healed up?

A. That's right.

Q. Maybe it was placed superficially;

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correct?
A. Within a couple of days, that is not the mesh causing -- now, it will impair healing, because there's a foreign body reaction to things. But it's not due to degradation.
Q. Well --
A. If somebody is occurring longer than that, let's say beyond the initial healing period. Six weeks is traditionally where the body will be at roughly 98 percent of its strength. That's our usual, going by that six weeks. Beyond that, if exposure or an event like that occurs, degradation in my opinion is going to be one of the main underlying factors for it, in combination with the infection, inflammatory response.
Q. And what's the methodology for that statement?
A. Exact -- based upon the literature and my clinical experience on a daily basis, including in the past two weeks, four -- three TVT and one TVT-Secur patient I dealt with.
Q. Let's talk about the literature because I can't go and look at your charts, okay.
In the literature, what studies show that if an exposure occurs beyond six weeks did

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degradation play a major role, I think you said?
A. Then we go back -- let's go back to Clave then. And we've said -- we've admitted roughly 45 percent of those patients had degradation. Okay. So based purely and just on that paper, that will be my opinion, that 45 percent for that paper.
But what I'm saying is it has been inadequately studied elsewhere. Something that needs to be done.
Q. Did Clave rule out other causal factors for the exposures in his study?
A. I have --
Q. If he did, tell me how he did it.
A. No. I would have to look at the paper and see all that he's looked at.
Q. This study you talk about that you think Ethicon should have done, how would you design that study?
A. The basic unfortunate reality is it -- I don't know if it could be done. Hence the reason why I am anti-mesh in the vagina, because you cannot safely make this thing work and cannot do it in a long-term.
Q. When you say that there are some

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patients who have mesh who have devastating complications, that's a statement you'd made earlier; correct?
A. Multiple times that's based on my clinical experience in talking and discussing it with surgical colleagues.
Q. So you're not relying on any literature to report the rates of devastating complications with TVT retropubic; correct?
MR. CARTMELL: Not relying on what? Object to the form of that.
A. No. I think certain patients -- certain patients.
Certain studies like Hou, et al., which was also Phillippe Zimmern, who I personally talked to about his paper, where they had slings, where after -- they had only removed for pain. 19 percent had persistent pain. Just to beat you to the punch, they did not break it down into TVT or not.
Q BY MR. SNELL: And they also didn't report a denominator from which all those patients were drawn from; correct?
A. They did not. That denominator, as far as I know, is not known.

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Q. And that's an issue with case series, where you do not have a denominator, thus one cannot compute reliably the incidence; correct?
A. The true incidence, unfortunately, is not known, and it needs to be known because some of these people's lives are destroyed.
Q. So in a case series like you mentioned, a major limitation to that series is that it does not speak to the incidence of those complications; correct?
A. I would disagree with you that it's a major limitation. It is a limit you cannot extrapolate across the board, but in his series, in a very good reconstructive surgeon's hands, 19 percent of SUIs had persistent chronic pain.
Q. And you don't know how many were TVT; correct?
A. That is correct.
Q. More likely than not, they were not going to have persistent pain; correct?
MR. CARTMELL: Object to the form. I think it's vague and ambiguous. May call for speculation.
A. Oh, I see what you're saying. Okay.
In the follow-up of these individuals,

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there were 19 percent that had permanent pain. Statically speaking, that means that you get rid of the mesh, 81 percent got better. Therefore, the mesh is the source for the pain.

MR. SNELL: Move to strike.

Q BY MR. SNELL: It was more likely that the patients would get better as opposed to having persistent pain in the study you just told me about; correct?

A. During the duration of their follow-up, 81 percent of the patients, once the mesh was relieved, had resolution of their pain.

Q. You wrote in your report that you believe that the TVT mesh is cytotoxic?

A. Correct.

Q. You saw that cytotoxicity -- that data were presented to the FDA in the 510K for TVT; right? I can withdraw it and clean it up.

Dr. Elliott, you saw that, in the 510K for TVT retropubic device to treat stress incontinence, Ethicon reported the cytotoxicity data that you reference in your report to the FDA; right?

A. I don't -- it's been a long time since I read the 510K submission. I have to look to see

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if they talk about the severely cytotoxic, marked cytotoxic part of these studies.

Q. You know in 2013 the FDA released a statement regarding synthetic slings for the treatment of stress incontinence?

A. They had a release.

Q. And you saw the FDA wrote in that release that the full length mid-urethral sling like TVT retropubic device has been shown to be safe and effective up to one year; correct?

A. I would have to see that study. And let's just -- or not the study. But that publication. But let's just say they say that exactly as you did.

At one year.

Q. Right.

A. Again, that's the limitation of all those statements.

Q. And has the FDA, to your knowledge, ever concluded that the TVT retropubic device -- that the mesh is cytotoxic?

A. I have not seen that in any of their writings. I don't know also what information they've received.

Q. You have not seen any documents from

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the FDA and the people what reviewed the TVT retropubic device 510K with regard to their determination as to whether the TVT retropubic device is safe and effective?

A. No. I mean, I've seen that the -- that the FDA has made those statements. But what I'm saying is, I don't know if they've received all of the documentation and then their opinions on that, as far as the cytotoxicity, et cetera.

Q. Okay.

(Exhibit 23 marked.)

Q BY MR. SNELL: I marked as Exhibit 23 the FDA's statement, Considerations about Surgical Mesh for SUI, 2013.

This is a document you're familiar with?

A. Correct.

Q. And you see this is off the FDA web site as well?

A. That is correct.

Q. Page last updated March 27, 2013; correct? I'll show you?

A. Yes, I see it.

Q. And it says on the first page, "the safety and effectiveness of multi-incision slings

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is well established in clinical trials that followed patients for up to one year. Longer follow-up data is available in the literature, but there are fewer of these long-term studies compared to studies with one-year follow-up."

Correct?

A. Correct. That's what they state.

Q. Let me ask you this question.

It would be a true statement that the safety and effectiveness of the Burch colposuspension, the autologous slings, biologic slings, cadaveric slings, all the different stress incontinence options -- that the safety and effectiveness of them has been assessed more, to a greater volume in studies reporting on 12 months or less as compared to longer term studies; correct?

MR. CARTMELL: Object to the form.

A. That would be true, that most SUI studies are short-term because they're easier to do, and that's why the data is poor to moderately poor.

Q BY MR. SNELL: So what you just said there, let me make sure I understand you.

Shorter term studies assessing stress

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urinary incontinence surgery are easier to do than longer term studies?
A. Correct.
Q. That applies across the board?
A. Correct. I mean, shorter term studies are easier to do because they're short-term. You have less patient loss to follow-up those things.
Q. What studies, if any, in women show that cytotoxicity causes any complications with the use of TVT retropubic device?
A. There have been none because the issue of cytotoxicity has not been released to the general public. Therefore, someone is not going to study that if they don't even know it exists.
Q. Do you know the 510K documents on TVT are publicly available at the FDA and available through a Google search on the web sites?
A. They may be. I don't -- I don't know because I don't search that.
Q. You've never attempted that search?
A. Not with this device. I've done it with the ObTape, and I couldn't find it.
Q. Okay. Are there any complications that you believe are due to cytotoxicity?
A. Possible --

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Q. Let me make sure because I want to focus on TVT, not leave a vague question out there because we were last talking about ObTape.
So for the TVT retropubic device, are there complications which you believe are caused by cytotoxicity?
A. In theory, possibly all of them, because cytotoxicity is cell death. Cell death will increase the foreign body response, the inflammatory response, subsequently increase the degradation, cracking, increase pain, increase the potential for infection. I'm saying possibly. It could be.
Q. Okay.
A. That has not been studied to date.
Q. Okay. For example, you pointed me to the Wang paper earlier, and we looked at it, and there was a 2.4 percent rate of exposure; right?
A. There was 17 out of 700 that had impaired vaginal healing. And I can't recall the data beyond that.
Q. It was 2.4 percent?
A. Okay. I remember the 2.4 percent.
Q. Okay. So working with that number, 2.4 percent, and we looked and there was more than

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60 months follow-up.
Of that 2.4 percent, can you say how many of those 17 patients had the defective vaginal healing because of cytotoxicity, or is that known?
A. That has not been studied to date, because as I mentioned, I didn't even know the cytotoxicity report even existed until I got involved in this. So no one out in the community, our physicians, researchers are going to know that exists. They're not going to study it.
Q. What percent of TVT retropubic devices is the mesh cytotoxic?
A. Well, from what they state here, if this TVT is studied and has been shown to have marked cytotoxicity or severely cytotoxic in these two references and that mesh is put in the patient, then 100 percent of those have the potential for cytotoxicity.
Q. All right. So if 100 percent have a cytotoxic mesh, why is it that 97.6 percent in the Wang study who were followed out beyond 60 months didn't have any defective vaginal healing?
A. It's going to be, again, multifactorial. The vaginal healing, the duration

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of follow-up, is smoking going to play a role, obesity, impaired vaginal status. And, again, what's going to be these people 15, 20, 30 years from now.
MR. SNELL: Move to strike as nonresponsive.
Q. BY MR. SNELL: My question was: If 100 percent of people have the cytotoxic TVT retropubic mesh, why is it that 97.6 percent of the patients in Wang did not have the defective vaginal healing?
A. See the -- not to be critical, but your logic is impaired. 100 percent of people who smoke don't get lung cancer. 100 percent of people exposed to asbestos don't get mesothelioma. 100 percent exposed to TVT aren't going to have those devastating complications, but certain ones do.
Q. And that's what I'm trying to understand and test here. All right.
What is it about the 97.6 percent of the patients who didn't have defective vaginal healing that led this cytotoxic mesh to have no role or no effect on the --
A. Okay. We decreased it down. You said

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defective vaginal healing.
Q. I was trying to use the words you said.
A. You're correct; 2.4 percent had defective vaginal healing. That is just one of the complications. Not all cytotoxicity or degradation is going to go just to mesh extrusion. I'm talking pain, contraction, roping, the degradation process. Pelvic pain, vaginal pain, dyspareunia.
So they are just saying, just in this limiting it, 2.4 percent had defective vaginal healing. Okay. So that's narrowing the number I talked about before, okay. I cannot answer the question as to why don't all. All I know is that to me this is a red flag and patients and doctors need to be warned of that possible cytotoxicity.
Q. For example, we looked at the number of patients who reported dyspareunia and there was four out of that group.
A. Five complained of pain. Four complained of dyspareunia, and then five complained of vaginal bleeding.
Q. Right. So for the dyspareunia, right -- we addressed this somewhat. I will

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represent to you I calculated that, and it's 0.56 percent. Okay. 4 out of 700.
For that 0.56 percent of patients who had dyspareunia, is there a way to scientifically reliably say, which, if any of them, that was caused by cytotoxicity? And if there is, I want to know the methodology by which you would conclude that.
A. That would require a study by Ethicon to do that. And so all I know is we have a red flag. We have marked cytotoxicity. We have complication. These are just limiting to the specific one. I cannot point to a paper and say that because then it has not been studied because individuals didn't know to study it. It needs to be studied, though.
Q. So I think in fairness, the answer to my question was, no, you don't know that; correct?
MR. CARTMELL: Objection. Asked and answered. He just answered your question.
A. No. And I will reiterate just what I said again. Cytotoxicity is a red flag of something going on. We know there's cytotoxicity there. How much of a role it plays in all the other complications, I don't know. That needs to

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be studied.
Q BY MR. SNELL: Okay. That was my question.
Of -- and I was really focused on dyspareunia. Of the four patients with dyspareunia, you can't say, reliably, scientifically, which if any of those four were caused by cytotoxicity; correct?
A. No. You are correct because all I can say is there was some defect in the product that caused this. I cannot attribute that just to cytotoxicity.
Q. And Wang did not rule out other factors besides the mesh; did he?
A. I don't recall Wang giving a specific opinion on that, what necessitated.
Q. How would you design a study like you state Ethicon should do with regard to cytotoxicity to see what effect, if any, it would have on complications for women receiving the TVT retropubic device for stress incontinence?
A. You cannot ethically construct a study of putting a product in that has the possibility of cytotoxicity in a patient for a quality of life study. You can't do it. It would never get

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approved and no woman would accept it.
Q. Am I correct that for the pore size of the TVT mesh you cannot reliably say scientifically what complications are caused due to pore size in TVT patients?
MR. CARTMELL: Object to the form.
A. As I've stated multiple times, as outlined in my report, we have an overall system design failure.
Specifically small pore, what role is that playing in percentage of the complications. No, I cannot state that.
Q BY MR. SNELL: You have not studied the rates of complications of stress urinary incontinence slings to see whether there is a statistically significant different rate of complications that occurs dependent upon pore size; correct?
A. You are partly correct. However, we do know from the hernia mesh data and the Vypro mesh data that complications can be reduced with a large poor lightweight. It has not been extended down into the TVT like it should have been. So you are correct. That data does not exist and it should exist.

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Q. Actually, that data do exist to some degree in the application of stress urinary incontinence because there are data like the Cochrane Reviews that show that multifilament meshes have higher complication rates than monofilament meshes; correct?
A. Yes. But we're talking about the TVT here. And I'm talking about lightweight hernia mesh. You know, Ethicon employees all agree, lightweight, small -- or large pore reduce complications. The Cochrane has nothing to do with lightweight, large pore meshes. It doesn't exist, as far as I know, for slings.
Q. The multifilament meshes assessed in the Cochrane Review that had higher rates of complications compared to the monofilament meshes like TVT have a smaller pore size than the TVT mesh; correct?
A. No. You are correct, but we're talking -- yes, I agree with you.
The ObTape, the ProteGen, the Gortexes, the Amid 3's have higher implications than TVT. I agree with you. But what I'm saying is the next level up above TVT, the lightweight, large pore meshes, it does not exist. The

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technology exists for it, but the product has not been done in any studies for women in stress incontinence.
Q. Right. Okay. So those larger pore, lighter weight meshes have not been cut down to 1.1 centimeters, put into sheaths and tested by anyone; correct?
A. That is correct. In my opinion it should have been.
Q. All right. What physicians and surgeons -- well, strike that.
If physicians and surgeons wanted to test larger pore, lighter weight hernia meshes in the application of stress incontinence, couldn't they cut slings made of ULTRAPRO and test it for incontinence?
A. I can't speak to what surgeons could or could not do.
Q. Well, you cut mesh and put it in the body however you wanted; didn't you?
A. No.
Q. You didn't do that for sacrocolpopexy?
A. I configured an already Y-shaped mesh. I did not take something and create something new. I just configured it to fit into the patient's

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body.
Q. No surgeon in the world that you're aware of has ever taken a larger pore, lighter weight hernia mesh, cut it down to 1.1 centimeters, put it in a sheath and placed it retropubicly, like the TVT retropubic device; correct?
A. I am unaware of anybody doing that. Including Ethicon.
Q. Therefore, you are unaware of any studies in the application of a stress urinary incontinence tape that show that when put in that configuration and used as the TVT is, retropubicly, with the passage of trochars, that there is a lower complication rate in stress incontinent women; correct?
MR. CARTMELL: Object to the form. I believe it misstates his opinions in this case and the report.
Q. BY MR. SNELL: Go ahead.
A. And therein lies a huge deficit of what Ethicon should have done. They knew the data on hernia meshes and prolapse meshes. Large pore, lightweight fewer complications. They did not take the next step of extrapolating that to TVT,

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because, as they said, now their TVT data no longer holds up. So they made a decision not to do that.
Q BY MR. SNELL: Well, you would criticize Ethicon for wanting to have a product that has longer term data than all the other meshes out there, including ones you, yourself, have used?
MR. CARTMELL: Objection. Argumentative.
A. Well, I have no problem with them having long-term studies out there, but I'm saying they're not focused on safety. And I'm saying if they knew, if a corporation knew that there were a better product available and they chose not to, purely for marketing, that is unethical, unacceptable.
Q BY MR. SNELL: How do they know it's better in the application of stress urinary incontinence when the sling is only 1.1 centimeters?
A. They should --
MR. CARTMELL: Object to the form. I don't understand the question.
A. No.

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MR. SNELL: I mean, you're -- I mean, what you're talking about is Ethicon's state of mind, and that will not fly with this judge. So I'm going to withdraw that question.
MR. CARTMELL: Let's take a break.
MR. SNELL: That's fine.
(Recessed from 4:25 p.m. to 4:42 p.m.)
MR. SNELL: You do know that I'm here to question him on his New Jersey report as well?
MR. CARTMELL: No, I didn't know that.
MR. SNELL: Ben didn't tell you that?
MR. CARTMELL: Hum-um.
MR. SNELL: He said he wanted it all done in one sitting. So --
MR. CARTMELL: He told me next week in Minneapolis.
MR. SNELL: That's only case specific on Watkins. I'm doing the New Jersey general stuff today.
MR. CARTMELL: Okay.
MR. SNELL: That's what they told me.
MR. CARTMELL: I'm not doing that. If you're telling me you're going longer than 7 hours --

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MR. SNELL: Yeah.
MR. CARTMELL: -- I ain't doing that.
MR. SNELL: Well, why didn't Ben tell you that, because that's the agreement.
MR. CARTMELL: Nobody told me that.
MR. SNELL: That's the agreement I put in the emails, too. Ben was having --
MR. CARTMELL: This was the consolidation deposition.
MR. SNELL: Right. And then but Ben said, but you need to do his New Jersey generally TVT at the same sitting because Watkins case specific is next week. And I said, okay, I'll start that after I finish the design defect. It's all in the emails. I'm surprised he did not tell you that.
MR. CARTMELL: He didn't tell me and I'm not doing it.
MR. SNELL: Is that on the record. I mean, because I came here and flew here to do both. And I'm not available next weekend, okay, because I have my own experts.
MR. CARTMELL: I'm not available tonight, and I -- I agreed to do this, and I have something I have to be at at 6:00, and if I'm not

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there at 6:00, I'm going to get my brains beat in. I'm not doing that.
MR. SNELL: Well, then we're going to have to agree that whenever I can make it and the doctor make it, we'll do the New Jersey general TVT portion.
MR. CARTMELL: Well, that's fine. But I'm not --
MR. SNELL: Because the person who's deposing him in Watkins --
MR. CARTMELL: Look, there's --
MR. SNELL: Let me just say something.
MR. CARTMELL: This is ridiculous that you take 7-hour depositions.
MR. SNELL: The person disposing him in Watkins is only case specific. That was all agreed to and hammered out --
MR. CARTMELL: Nobody told me that.
MR. SNELL: -- between Ben and everybody in these big mass emails. All right. Well, let's just -- let's jump on it, okay.
MR. CARTMELL: Okay.
MR. SNELL: We'll find something that works. But I'm telling you -- and you know it. I know you're tied up and I'm tied up, through the

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5th, okay. But I'm here today, prepared to do the New Jersey general after this one.
MR. CARTMELL: Well, I'm not.
MR. SNELL: I know. I know.
MR. CARTMELL: I'm not doing that. I'm not doing 9 hours --
MR. SNELL: I don't know why they didn't tell you.
MR. CARTMELL: I'm not making the doctor do 9 hours of deposition. That's ridiculous. This is crazy. We're, again, going over stuff that I think you even covered in his first depo.
MR. SNELL: I've only deposed him on Prolift.
MR. CARTMELL: But that doesn't matter. A lot of this stuff has been talked about.
MR. SNELL: No. But this is in the application of the design of TVT for stress incontinence. That was the agreement.
MR. CARTMELL: Go. You've got 48 minutes.
MR. SNELL: That was the agreement, okay. That's why I came here. And I'm prepared

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to do that.
MR. CARTMELL: I wish I had known.
MR. SNELL: I wish they would have told you, to be honest with you. And I wish they would have told me, because I was preparing to go out tomorrow. And as for the length of deposition being ridiculous, in New Jersey some of my experts were deposed for more than 13 hours.
MR. CARTMELL: I just can't believe this. But go ahead.
MR. SNELL: All right. So we'll pick it up. Are you ready, Doc.
THE DEPONENT: Yes, I am.
Q BY MR. SNELL: You got your report there handy?
A. Yes, I do.
Q. Can you just turn to page 20.
A. Yes.
Q. The picture there, that is not a picture of the TVT retropubic device to treat stress urinary incontinence; is that correct?
A. That is correct.
Q. All right. The width of whatever that mesh is is a lot more than 1 centimeter; correct?
A. I don't know the dimensions on that.

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I have to go back to the original document.
Q. Well, if you look at the number of pores all the way across it, you and I can agree that that's a lot more than 1 centimeter wide; correct.
MR. CARTMELL: Object to the form.
A. Again, I can't say. I just don't know. I'm saying I don't know what it is. I'm not disagreeing with you. I just don't know.
Q BY MR. SNELL: There's no sheath on that mesh; correct?
A. That is correct.
Q. And there's certainly no trochars connected to it; correct?
A. That is correct.
Q. And you don't know how that -- whatever mesh it was stretched; is that correct?
A. I'd have to go back to the original document and see what they said.
Q. Okay. Are you aware of any studies that have looked at potential shrinkage with the TVT device in the application of stress incontinence treatment that report that there was no shrinkage with the TVT?
A. We'd have to go to the contraction

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section of my report, which I have down here starting on roughly page 17, it appears.
In there I say, Ethicon's medical director stated that TVT can shrink -- generally believe TVT mesh would shrink approximately 30 percent post implantation, and that is an internal document.
MR. SNELL: So respectfully move to strike.
Q. BY MR. SNELL: My question was: Are you aware of any clinical studies that assess the TVT in the application of stress urinary incontinence and reported that there was no shrinkage with the TVT mesh?
A. That there was no shrinkage? I'm unaware of any studies that's documented no shrinkage.
Q. Okay. The Vypro mesh, you're aware that -- let me back up.
So you make reference to Vypro and ULTRAPRO in your report; I believe; correct?
A. Vypro. I'd have to look and see with ULTRAPRO, where I put that. But Vypro, yes.
Q. In the context of a hernia or animal study; correct?

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A. That's correct. On page 21 of my report.
Q. You know Vypro was assessed even for the application of prolapse and was found to have a greater than 10 percent exposure rate; right?
A. That is correct. But it was less than the existing Gynemesh.
Q. Actually it was assessed and it was found to be 17 percent and Dr. Jacquetin found that it was not tolerated by the body.
A. Okay.
Q. Is that correct?
A. I don't recall that. I have no reason to doubt that it's incorrect.
Q. Okay. And the ULTRAPRO, you're aware that that was ultimately put into the Prolift Plus, and there were mesh exposures with that mesh in the POP application; correct?
MR. CARTMELL: Object to the form. Go ahead.
A. Yes. Again, and that reinforces my opinion. Mesh should not be placed in the vagina.
Can we just -- I'm sorry to interrupt -- deflect the curtain the opposite direction. Thank you. Feel like God there for a

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second; I was glowing.
Q BY MR. SNELL: You know that Dr. Jacquetin in the TVM group assessed Vypro in the transvaginal mesh pelvic organ prolapse application?
A. That is correct. I've read that, yes.
Q. And they found that tolerance of that material was poor?
MR. CARTMELL: Object to the form. You got the study. Show it to him. I think -- I think you're misstating the study.
Q BY MR. SNELL: You're aware of that; correct?
A. I am aware that they did look at it. I am not aware of the specific details of that study. It's been a while since I looked at that study.
Q. I have it here on the computer.
A. That's fine. Which name or title is it? Or who's the lead author?
Q BY MR. SNELL: Denis, D-e-n-i-s.
A. Okay.
Q. Denis, Jacquetin. Here you better -- okay. You need to maximize -- there you go?
A. Oh, so it's an abstract.

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Q. Right.
A. Okay.
Q. You see that they reported the tolerance was poor?
A. Let me go to their conclusions.
Q. Can I come around and look at it with you.
A. By all means.
Q. Because it's electronic, just so the record reflects -- it says in this study that tolerance of the Vypro mesh is VERY poor; correct?
A. That's what it states, yes.
Q. High rate of erosion, and problems of cicatrisation have been observed.
A. Correct. C-i-c-a-t-r-i-s-a-t-i-o-n, which just means scars.
Q. Okay.
A. Contraction.
Q. And it also had complications of retraction and rigidity were observed with the Vypro mesh?
A. That is correct.
Q. Frequently with clinical severe consequences; correct?
A. That is correct.

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Q. And they talk about the use of a half absorbable mesh does not seem to reduce inflammation and could even accentuate it; correct?
A. That's correct. All right. And then they go on to say, "Good results of the TVT does not seem to be much modified by the additional" -- okay. That's separate.
Q. Your understanding --
A. I have to see if that Vypro -- they mentioned a bioabsorbable, is if they have Vicryl in there --
Q. Right.
A. -- or a collagen base of some sort. That's associated with increased inflammation.
MR. CARTMELL: Hey, put the name of that study and the citation to it on the record, please.
MR. SNELL: Yeah. Denis, D-e-n-i-s, Abstract 620. It was an abstract presentation. And Dr. Jacquetin there, too. All of the study subjects coming out of Clermont-Ferrand. Abstract 620 at the joint ICS/IUGA 2004 conference in Paris, France. I'll make that representation. I know that's where this is from.

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THE DEPONENT: And I was at that meeting.
Q BY MR. SNELL: Did you see this presentation?
A. I don't recall seeing it, no.
Q. And you know the Vypro mesh, it's a larger pore mesh than the mesh used in the TVT device; correct?
A. It is.
Q. And the Vypro mesh uses a combination of Vicryl with the Prolene polypropylene; correct?
A. Again, I'd have to refresh my memory. That is my recollection. It is partially absorbable.
Q. All right. The Vicryl part is what absorbs over time?
A. That is correct.
Q. And the Prolene polypropylene mesh is what's left behind; correct?
A. That is the permanent portion of the implant, yes.
MR. SNELL: Let's mark this.
(Exhibit 24 marked.)
Q BY MR. SNELL: Exhibit 24 is a study of various meshes, fascia, animal, cadaveric

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materials, and the rabbit model with implications for sling surgery; correct?
A. That is correct.
Q. This is a paper you were one of the authors of; correct?
A. I was the lead author.
Q. Okay. And this was published in the Journal of Urology?
A. Correct. In 2004.
Q. All right. Is the Journal of Urology -- does it have a poor peer review process?
A. A poor, meaning incompetent? I mean --
Q. Okay.
A. As opposed to pore, p-o-r-e? You're talking poor, p-o-o-r?
Q. Yes, sir, p-o-o-r.
A. No. It would -- in urology, it is probably one of the most strict peer review, along with the European Urology Journal.
Q. All right. So among the various things assessed, one was polypropylene mesh. Another was autologous fascia; correct?
A. That is correct. And it was the Sparc

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that we used.
Q. And Sparc was a -- that was a monofilament polypropylene mesh; correct?
A. Correct. Quite similar to TVT.
Q. And there was a rapid loss of strength and stiffness in the porcine and cadaveric materials; correct?
A. That is correct.
Q. And the autologous fascia, as well as small intestinal submucosa demonstrated the highest rate of contraction; correct?
A. In this short-term limited, yes, that's what we found.
Q. Does the autologous fascia contract in the human body?
A. It is reabsorbed. And remodeled is the term we usually use. As opposed to contraction.
Q. I saw in your pilot study with the 10 patients with the transobturator autologous sling that you reported that you placed that sling loosely in order to hopefully minimize contraction of the autologous tissues.
Do you recall that statement?
A. I don't recall that statement per se.

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However, in the first 10 patients we didn't know the tensioning of this. No one had ever done it before. And so we're accounting for a lot of different factors. Is it going to -- is it going to tighten up or is it going to stretch out. We didn't know.
Q. Okay.
A. And that's why it's a feasibility study.
Q. Okay. The last page you talk about "the polypropylene mesh has extremely low stiffness at baseline, but it demonstrated increasing stiffness with time. This phenomenon is likely caused by the ingrowth of tissues into the interstices of the mesh."
A. That's correct. That's what we stated.
Q. Is that an accurate statement?
A. That is an accurate statement of what we found. We did not know at that point in time the potential implications of that.
Q. You concluded that the biomechanical results of the current study support the use of polypropylene mesh for sling surgery relative to other non-autologous materials; right?

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A. Again, that's what we stated as of 2004 in our short-term study because we found the increased stiffness and thought that that would be increased as far as efficacy. And we didn't realize that that process continues.
Q. You published a subsequent study in follow-up; correct?
A. Correct. By Krambeck, et al.
MR. SNELL: Go off the record for a second.
(Exhibit 25 marked.)
Q BY MR. SNELL: So-Exhibit 25, Doctor, is your follow-up study that you published in 2006 in the Urology Journal; correct?
A. Correct.
Q. And this was a study where you found significant differences were found for inflammation, eosinophil infiltrate and inflammatory rind at 12 weeks with polypropylene mesh having the lowest degree; correct?
A. That was one of our findings.
Q. And that was a study looking at polypropylene mesh versus cadaveric fascia, porcine dermis, porcine small intestine submucosa, and autologous fascia; correct?

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A. Those were all the properties or the substances we studied.
Q. All right. And you reported that the inflammation with the cadaveric fascia and porcine may cause rapid clinical deterioration compared to the autologous fascia and polypropylene mesh?
A. That is correct. That was the main purpose of this study, looking at what happens to the cadaveric and porcine materials. Does the body rapidly absorb them, which we found out it did. And the polypropylene had the greatest degree of scar formation.
Q. And that's one of the reasons why cadaveric fascia and porcine materials for use in the sling application never really caught on to a large degree because, with longer term follow-up surgeons found that those slings would actually be absorbed into the body; correct?
A. Partly correct. The porcine, no question. The porcine dermis and then the porcine SIS, in my opinion, were horrible products. I used them and they failed miserably. It was worthless to do that. Actually worse than worthless.
The -- I forget the rest of what your

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statements were. But the --
Q. Cadaveric. With regard to the cadaveric.
A. And the cadaveric -- there's multiple different types of cadaveric and how they are processed. And some are good and some are not good. The one we found here raised questionable results.
Q. How do you know which ones are good and not good until you try them?
A. That's a major problem, but pretty much agreed upon, freeze died eradiated cadaverics have a higher -- not degradation. Decomposition. De --
Q. The eradiation process that you need to do to cadaveric tissue to reduce any potential transmission of disease is known to cause those materials to degrade; correct?
A. Yes.
Q. And you wrote here that the fibrosis and scarring noted with the polypropylene mesh may also contribute to a more lasting repair; correct?
A. You're correct. That was at that point in time the conclusions that we reached. And we subsequently discovered that we were

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incorrect with that. We had our facts right, our conclusion wrong.
Q. You wrote that the facial slings using harvested autologous fascia which increases operative time and patient morbidity.
And that's true as of today; correct?
A. I would not disagree with that.
Q. And you report other studies have shown a decrease in tensile strength of cadaveric fascia; correct?
A. Correct. But the issue was -- we assumed at that point in time that increasing tensile strength was a good thing. We're now realizing that the pelvis and the vagina are elastic and have to bend, and so we're not necessarily agreeing with the conclusions I had in this study.
Q. You found that the xenograft and cadaveric products demonstrated high degrees of inflammatory infiltrate; correct?
A. That is correct. Specifically with the SIS. And those had a significant immune response to it. Yes. And those are not used in our practice at all anymore because of that.
Q. Okay. What is the significance of the

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SIS for the porcine? Is that a single incision sling?
A. No. It's just like -- instead of using cadaveric tissue for the sling, we use SIS, which is pig intestine, submucosal pig intestines. There's also porcine dermis, but both of them contain porcine DNA and are not recommended to be used.
Q. And you're right. "We also noted a low degree of inflammation with polypropylene mesh compared to the other materials."
A. Yes. And that's a relative statement in the short-term in the rabbit model compared to the processes that we know create a significant amount of immune response because they still have porcine DNA. So there's a major foreign body reaction to that.
Q. And you found that there was a low degree of inflammation with polypropylene mesh, which was similar to what was seen with the autologous fascia; correct?
A. Correct. In the short-term that is correct. That's what we found.
Q. And so the polypropylene mesh in your study acted most closely to the autologous fascia;

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correct?
A. Correct. In the rabbit model, placed transabdominally, that is the conclusions we reached in 2008.
Q. All right. I mean, some of the studies you cite to are in dogs and other animals that are not even in the sling application like you tried to do; right?
A. I agree.
Q. So are you saying that your study is not important, or that --
A. No.
Q. -- the findings are inaccurate?
A. No. I'm saying it has to be looked at as far as -- this is looking what the rabbit model does to these various different slings in the short-term. I think they're very important findings.
Q. You say, our results -- "the alternatives to biologic material, synthetics are gaining popularity. The polypropylene mesh has shown promising initial and long-term results similar to that of autologous sling material"; correct?
A. Correct.

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Q. And then you go on to say, "Our results indicated little degree of inflammation and significant fibrosis similar to that with autologous material"; correct?
A. Correct. And that is the significant finding of that, which we did not correctly interpret our results at that point in time.
Q. Well, you've stated significantly that none of the material appeared grossly infected at explantation in your study either; is that right?
A. That's correct. In the rabbit model placed transabdominally, that is correct.
Q. All right. I think in your report somewhere you mentioned -- and maybe I'm misstating this, but you were relying on -- or you found something important coming out of the UCLA Grand Rounds?
A. No. No. I don't recall that.
Q. Okay.
A. I attended multiple UCLA meetings which involved discussions of meshes, but I think that's the only thing I could --
Q. Okay.
A. I don't think I ever attended what we call Grand Rounds.

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Q. You say UCLA State of the Art Urology Meeting --
A. Oh. Oh.
Q. -- page 4.
A. That's a yearly meeting that they have that Raz and other experts discuss. That was an attendance-only meeting. That's not Grand Rounds.
Q. Okay. I'm sorry.
A. No.
Q. Were you just kind of -- were you identifying different conferences or meetings you go to typically?
A. Correct. That was continuing medical education.
Q. Okay.
A. Where specifically UCLA is well-known for having Dr. Raz there. So there's always a strong female urology section to it. That's all that's stating.
Q. Dr. Raz is one of the proponents of needle suspension procedures over the years; correct?
A. Well, he used to be. He's not anymore. He doesn't do his own procedure anymore.
Q. Why not?

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A. Didn't work.
Q. Okay. Do you have that Ford Cochrane Review you cited to in your expert report handy? I think it was one of the first exhibits we marked. Can I just turn to a page. I have a question for you.
With the 2.1 percent mesh exposure rate they saw with the retropubic sling in the Ford Cochrane Review of 2015, would there be a scientifically reliable way of stating which, if any, of those exposures occurred due to the mechanically cut nature of the mesh?
A. You have to look at those studies and see when they were published. If they're published prior to 2007, you could say all of them were attributed. If they're published after that we don't know, and they'd have to look at the studies, see if they break it down in mechanical versus laser.
Q. Do any of the randomized control trials report that there was a sawing effect with the TVT mechanically cut mesh in the treatment of stress incontinence?
A. I have not seen that in the literature. That is based upon my personal

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experience with Sparc, not the TVT, and then also internal documentation.
Q. So if there was a 2.1 percent rate -- if there was a 2.1 percent rate of exposure with the retropubic TVT sling -- and I want you to assume that all of those were mechanically cut, okay -- how would you scientifically, reliably ascertain which of those 21 patients' exposures were because of the mechanical cut nature of the mesh?
A. Looking at this, I have no idea how many of these are TVT or not. It says retropubic slings, but that could be anything. It's not talking up-down, top-down, or anything. They're not comparing TVT right here necessarily.
So based upon that, I don't know how to answer your question because I don't know what they're looking at, because they just say retropubic.
Q. You didn't look and see how many of those studies were the TVT study?
A. I did not look through those to find out that information, no.
Q. So let me ask you this hypothetical then. If there were hypothetically 21 mesh

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exposures out of 1,000 TVT mechanically cut retropubic device cases, how would you -- would you be able to scientifically reliably say which of those 21 exposures were due to the mechanical cut nature of the mesh? And if so, how did you do that?
A. In a retrospective fashion, you would not be able to determine that with precision. You could say it's going to be a contributing factor in certain numbers. Also contributing could be degradation, infection, subclinical infection, all those things. In a retrospective fashion, you cannot. That's why it has to be done prospectively.
Q. And as you sit here today, you have never seen, in any prospective TVT retropubic study, any author attribute clinical mesh exposure due to a sawing of the mesh; correct?
A. I'd only have to go off of data on TVT-Secur and TVT -- TOT, the Hinoul study, but that is not a TVT study. To the best of my knowledge, that has not been evaluated. It should have been, but it has not been evaluated.
Q. The TVT-Secur, that was the laser cut mesh; correct?

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A. Correct.
Q. That study didn't assess the TVT retropubic mid-urethral sling to treat stress incontinence; correct?
A. Correct. It was TVT-Secur versus the TVTO.
Q. And the TVTO, in that study, do you recall if there were any mesh exposures?
A. I'd have to look at the study. I don't recall.
Q. Do you know if that TVTO mesh was mechanical cut?
A. The Secur was laser cut. And it was my understanding that the TVTO was mechanically cut.
Q. And the TVTO mechanically cut had a lower rate of exposure than the TVT-Secur; correct?
MR. CARTMELL: Tell him, if you know.
A. Again, I do not know. I'd have to look at the study.
Q BY MR. SNELL: Are there any data in women on the TVT used to treat stress incontinence which report how many, if any, of those TVT mechanically cut slings have a sawing effect?

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A. To the best of my knowledge, in those, they did not use that specific terminology. The fraying and the sawing is more from internal documentation of complaints coming into Ethicon and their discussions about it.
Q. Do any of the clinical studies on TVT used to treat stress incontinence report the mesh frame and its use in women?
A. Again, just like the last answer, I am unaware of any manuscript that discusses that specific terminology. That comes from internal documentation and also comes from my experience with the TVT, which did the same thing. But I didn't write on that either.
Q. Have you ever seen any scientifically reliable studies in women that document the incidents at which there is -- withdrawn.
I just didn't remember the word. You used two words, and I wanted to use one of them.
Have you ever seen any scientifically reliable studies in women utilizing the TVT retropubic device to treat incontinence that states the incidence of fraying of the mesh?
A. Again, this is -- what I stated before. I've not seen that in the literature,

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that specific terminology used. That comes from the internal documents and complaints that came in.

Q. Do you know the incidence for which fraying of TVT retropubic mesh in the treatment of stress incontinence occurs?

A. We have to go to my report on page 21, where I talk about fraying --

Q. Um-hum.

A. -- and particle loss, and the sawing effect. And the incidence -- okay. It varies -- as you go through the various sections here in the report on that.

Say on page 22, testing done by Ethicon. So that after elongation, 18 percent of the weight was lost due to particle loss. Pariente says the point -- 8.5 percent of the particle loss.

Q. But my question is specific to fraying. So what --

A. Fraying?

Q. Yes, sir. What -- I'm sorry. Yes, Doctor.

What's the incidence of fraying that occurs? I didn't see that number in your report.

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A. I don't think I state a specific number in there. However, during the placement of it, where, you know, they talk about 50 percent of these devices are elongated during the implantation with 12 pounds of force, that causes the -- to rope, fray, and particle loss. So I can't give you an exact percentage. But it is a constellation of problems that happen with that.

Q. Other than your paper on the use of the Holmium laser, have you published on treating any mesh complications?

A. Yes.

Q. Where? What paper would that be? For stress urinary incontinence?

A. Stress urinary incontinence.

Q. Yes.

A. I have the copy of my CV, which is an exact copy of yours.

My page 17 of 25, I have the Holmium laser complication, as you mentioned. And then number 9 on this is Clifton, et al., where I'm the senior author, of Repeat Anti-Incontinence Procedures Following a Sling Release.

So that's a study of individuals who had obstruction following a sling. We treated the

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obstruction, and then what happened to those individuals.

Q. What types of slings were those?

A. Those were all types of slings. Retropubic, suprapubic, transobturator, and vaginal.

Q. Were there any retropubic TVTs in that study?

A. I'd have to look and see what we documented.

Q. What was the main result of that study? What percent of the patients remained continent following sling release.

A. Again, I'd have to look at that study, the exact numbers on it.

Q. Do you have it with you?

A. Yes, I do. I should. Actually I don't have the paper. I would have to guess on the numbers. It was a high -- the issue was --

MR. CARTMELL: Don't guess. If you know, you know.

A. All I'll say is there's a high rate of reoperation once we cut the sling over time. That was the significant findings.

Q BY MR. SNELL: What do you mean by

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that?

A. What I mean is the traditional thought was, based upon a Webster paper, George Webster out of Duke, is that if you cut slings, 85 percent of people stayed dry. But the problem is no one had followed those individuals long-term. So we followed them long-term and found out that over time the rate of incontinence increased, requiring further treatment. So bottom line, it's not like if you obstruct somebody, you treat it, they're done. They're great. No, they have problems later.

Q. What was the mean time for your surgery to release the sling?

A. I'd have to look at the paper.

Q. Was it more than a year or less than a year?

A. I'd have to look at the paper. I don't recall and I don't, for some reason, have a copy of it here.

Q. What was the long-term follow-up that you say that you all conducted? How long was that?

A. Again, that's what I'm saying. I need to see the paper because I can't recall what the

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duration was.
Q. As you sit here today, do you know whether 50 percent or more -- strike that.
As sit here today, was it more likely than not that those papers who had a sling release would not require reoperation for incontinence?
A. I'll get the paper.
Q. Okay.
A. Because I can't recall.
Q. That's fine. I don't think I have it. So if you don't remember, that's fine.
MR. CARTMELL: You don't need to get the paper.
MR. SNELL: It would be good if he got the paper. But that's fine. If he doesn't remember his own data, that's fine. I'm not trying to trick him. I just want to know.
MR. CARTMELL: I mean, if you don't know the answer, then say you don't know, okay.
A. I don't know the exact number. We worked hard on it, and to do it justice, I'd have to find the paper.
Q BY MR. SNELL: Fair enough.
In your Holmium laser paper, the majority of women got better; right?

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A. At this point. But we are still continuing to follow those, and that's what was raised in the SUFU lecture when I talked about this. We don't know what's going to happen to these people long-term.
Q. Here, I have your paper. We have it here. Clifton, you said?
A. Clifton.
Q. This says median follow-up after release was 32 months. Of the 93 patients, 14 percent required repeat anti-incontinence procedure after sling realize.
A. Okay. All right.
Q. That's your paper; right?
A. I can't see the top of it. I'll assume you're telling me the truth, though.
That's it. Yes.
Q. All right. So actually, your data were consistent with other data in the literature, because 86 percent of your patients didn't require repeat anti-incontinence procedure; right?
A. I'll have to see the paper.
MR. SNELL: We can go off the record while he reviews that.
MR. CARTMELL: No. We're not going

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off the record while he reviews it.
MR. SNELL: It's his own paper. So you're going to waste my -- you're going to burn my time with him looking at his own paper?
MR. CARTMELL: You wanted him to look at it. This is your time, period.
Q. BY MR. SNELL: Okay. Doctor, could you quickly look at your own paper that you wrote?
A. 14 percent of patients after a sling release ultimately went on to a repeat operation. That's what we had in our data.
Q. All right. So that means 86 percent of those patients did not go on to a repeat sling operation?
A. Yes. But some of those elected not to because they were scared from previous surgeries.
Q. What percentage of the patients elected not to?
A. I'd have to look at the study. I don't have that. So I mean, that's -- again, I'd have to look at the study.
Q. Fair enough.
When you do your autologous fascial slings, and the transobturator autologous slings, how do you tension those slings?

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A. How do I tension them? I -- well, you said two different things. Pubovaginal or autologous transobturator. Which one?
Q. Either one. Or if there's a difference, just tell me there's a difference.
A. Well, there's a difference between the two.
Q. Fair enough. How do you tension autologous fascial slings?
A. Well, again, there's two different types. Pubovaginal or transobturator?
Q. Pubovaginal?
A. Pubovaginal, there's three steps to do this. Place a cystoscope in the urethra, deflect it 15 degrees. Up top in the abdomen, you tie initial knot that you can fit two finger breadths in it. Secure it with a clamp. Tie multiple knots. In doing that, you're fairly reproducible as far as the tension goes.
Q. Some surgeons use one finger breadth; correct?
A. It's -- you can -- yeah. Well, I can't speak to that. I do two finger breadths and it works.
Q. Is that because that's how you were

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taught to do that procedure?
A. Yeah, but I'm going to modify it. That's originally how -- oh, I was taught the leave a gap. The key is you leave it loose.
Q. Okay.
A. And so if you use one finger breadth or two finger breadths might not make all that difference because it's the distance from the fascia to your knot, not necessarily the width. So one finger breadth and two finger breadths is actually going to be the same.
Q. You don't really use any objective measurement to assess tension; correct?
A. That is an objective. 15 degrees and one finger breadth. So I have objective, reproducible data. And I have never had, in my pubovaginal slings, a patient go into retention that was not a purposeful retention.
Q. You don't use any type of gauge to assess tension on the sutures; correct?
A. That does not exist for the pubovaginal slings.
Q. All right. And is there any literature that reports on the effect, if any, of using one, two, or three suture finger breadths of

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detensioning for the autologous pubovaginal sling as opposed to some other method of tensioning?
A. No, there's nothing in the literature like that. The teaching is to leave it loose.
Q. And realizing you don't really do the Burch. Do you even remember how you were taught to tension or detension a Burch?
A. No, I don't remember that.
Q. What is wrong with the tensioning of the TVT retropubic device, if anything, in your opinion?
A. It's not reproducible. The pubovaginal sling, I can tell somebody exactly like I told you. Cystoscope in, deflect it 15 degrees, two finger breadths up, tie it loose, and you won't have retention.
TVT, it says tension free, but then there's tension. And so it's not reproducible. I can't tell you how to tension it correctly. I can tell you the pubovaginal sling.
Q. Well, with the pubovaginal sling, there is a fair number of patients who have urinary retention after that procedure; right?
A. I can't speak to those. I can speak to my own experience. Like I say, it's

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reproducible in my hands.
Q. Right. But you don't do all the sling surgeries in this country. So I'm more interested in out in the masses in the United States.
There is a fairly high rate of urinary retention following the autologous pubovaginal sling; right?
MR. CARTMELL: Object and move to strike the statement of counsel. Object to the form as well.
MR. SNELL: I'll withdraw the statement.
Q BY MR. SNELL: Let me just -- looking broadly, nationally, okay, across the data, there is a fairly high rate of urinary retention following autologous pubovaginal slings; correct?
MR. CARTMELL: Object to the form.
A. I can't agree with that. You say fairly high. I don't know that. I've not seen that data.
Q BY MR. SNELL: You've seen reports in the data of rates of retention higher than 20 percent following autologous pubovaginal sling?
A. It depends on how you're describing retention. If you're talking immediately

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postoperatively, yes, that is very commonly. That's why a suprapubic tube or intermittent catheterization is not uncommonly required. Permanent retention after a month or six weeks, that's debatable, the duration, should be very low. In experienced people's hands, it's essentially zero. Again, my hands zero.
Q. You've read the sister study by the -- that was funded by the NIH that compared the autologous pubovaginal fascial sling to the Burch colposuspension, and they found statistically significant higher rates of not only voiding dysfunction and retention but retention requiring reoperation in the autologous sling arms; correct?
A. That's been a long time since I've read it. I have to look at that paper. That was a good paper, but it's been a long time since I've seen it.
MR. CARTMELL: I don't mean to interrupt, but I'd like to check the time, please.
THE REPORTER: 7 hours and 13 minutes.
MR. CARTMELL: Okay. You're done. If you want to go -- I may have a few questions. But if -- if -- we can go off the record if you want and talk about what you and Ben agreed to. It's

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just nobody told me that, and I really need to be somewhere.
But let's go off the record right now.
MR. SNELL: Well, no. This needs to be put on the record, and I have emails documenting this, where Ben said, Burt, the MDL design defect dep and New Jersey general TVT dep have to done in one sitting on one day; you got to do it today. And I said, okay, Ben, I will. And then he and Judy Walberger, are doing the case specific Watkins deposition next weekend. So that was the agreement.
And I emailed Ben, fine, I'll do that. No problem. I'll start the New Jersey general TVT dep after this deposition, okay. And nobody ever said that that wasn't going to occur. And I came here with that expectation. And I wouldn't lie to you. I mean, you've seen the email. Were you on the email? It's in the email.
MR. CARTMELL: You don't have to answer that.
MR. SNELL: You don't have to answer. You're not under oath.
But with that said, what do you want to do? I understand you have to do something with

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your family.
MR. CARTMELL: We've been here nine hours, and I don't want to put him through -- if you told me you had 30 minutes or an hour, then maybe, but I mean --
MR. ROSENBLATT: Did they agree to extend any deadline? Will that work?
MR. CARTMELL: What's the deadline in New Jersey we're talking about?
MR. SNELL: I don't know. I think it's October 5th or something.
MR. ROSENBLATT: I don't know.
MR. CARTMELL: Let me make a call, okay.
MR. SNELL: Yeah.
MR. CARTMELL: I mean, I don't want to get anybody in trouble and all that, and I get the idea of having -- you know, doing them all at once. But I'm telling you, I knew nothing about this. And I think the idea of making a deposition -- you know, he's been here 9 hours. We've been on the record over 7 hours. That's hard. I don't know that I want him to continue this.
MR. ROSENBLATT: It wasn't Burt's

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idea.
MR. SNELL: Okay. Yeah, I mean, that wasn't my idea, okay. One.
Two, I understand. I know -- you know, look, I have a family, too, and I sympathize for you.
But, three, I came here with that intention and am ready to go.
And four, in New Jersey, my experts have been deposed for pretty much more than 12 hours in a sitting.
(Recessed from 5:33 p.m. to 5:42 p.m.)
MR. SNELL: So I will pass the witness in the MDL design defect case, and I reserve the right to do the New Jersey TVT general deposition, as I told Ben.
And I'm looking at my email that I sent to him, where I said, "That's fine. I will do my MDL design defect deposition first. And after that we will do the New Jersey general TVT deposition for anything that was not already addressed."
I'll stand by that statement I sent to Ben. I will not be duplicative. I really only

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have the warning stuff from my quick review of his report left over. So I am not foregoing my right to do that portion. And I will make a statement on the record that New Jersey, the deposition of an expert is not limited to 7 hours. My experts have been deposed in cases in New Jersey for well over 10 hours. But so that's my position. And I -- go ahead, Tom.
MR. CARTMELL: Okay. Just so it's clear. We took a break. I called Ben. He told me that the correspondence back and forth was -- or our position, I guess, that he stated was you needed to do both the New Jersey and the MDL deposition today, meaning in 7 hours, because there's a 7-hour requirement from the -- I'm just telling you what he said, from the MDL. And that the reports are the same. The general causation reports.
You just pointed out to me that in New Jersey there are failure-to-warn opinions that you have not yet been able to question the witness on. And I do agree with that. You have not done that.
You've said you wanted to continue the deposition for that. I had not been told -- and

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we've been here for 9 hours. I had not been told that that was going to happen today. I actually have a prior commitment that I really need to go to, and I believe the doctor is tired as well.

So I've agreed, and I think you have, too, that we would go ahead and allow you that time for the warnings opinions that you have and set it up at an additional time.

MR. SNELL: And at a mutually convenient date between doctor, myself, and whoever will defend.

MR. CARTMELL: That's right.

MR. SNELL: And I will just state for the record, too, Ben Anderson never told me he expected me to do both in 7 hours, nor does he have a basis under the New Jersey Rules of Procedure to make such a statement. I have my email that I sent to him, and there was no reply saying, no, Burt, you're wrong.

MR. CARTMELL: Okay.

MR. SNELL: But we have an agreement, and I'm passing the witness. Let's get this design defect deposition in the books.

MR. CARTMELL: Okay.

MR. SNELL: That way you can go do

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your thing.

MR. CARTMELL: Doctor, I just have a few follow-up questions.

You recall that you were asked previously about --

MR. SNELL: Can you give me one second, Tom. I'm essentially sorry to interrupt you. I just have to get something to write with. Very, very sorry. Go ahead. I'll shut up.

EXAMINATION

BY MR. CARTMELL:

Q. Do you recall being asked questions by Mr. Snell about large pore lightweight mesh?

A. Yes.

Q. And do you have an opinion within a reasonable degree of medical certainty that lightweight large pore mesh would lead to less complications in the TVT or in a mid-urethral sling than the TVT heavy weight small pore mesh?

A. Yes.

MR. SNELL: Objection. Leading. Go ahead.

A. Yes.

Q BY MR. CARTMELL: And what is your opinion?

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A. That based upon the medical literature, Klosterhalfen, Klinge, as stated in my report, lightweight large pore meshes have lower complication rates, and that is also including the internal Ethicon documents that state acknowledgment of that fact.

Q. You mentioned, when you were questioned by Mr. Snell, that the TVT, I believe you said during the first six weeks, may result in more pain.

Do you recall that?

MR. SNELL: Objection. Misstates.

A. I don't believe I said that. That the TVT may result in more pain? No, I didn't --

Q BY MR. CARTMELL: You didn't say that?

A. I didn't say that.

Q. I think you were talking about perioperative pain when comparing the TVT to maybe pubovaginal slings or the Burch.

A. Correct.

Q. Okay. When you were talking about pain during that perioperative period or during the first six weeks, what type of pain were you talking about?

A. I'm talking about incisional pain,

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pain in the suprapubic region, where the tissue may have been harvested. I'm not talking about vaginal discomfort. That would be equal. We're just giving the harvest area.

Q. Are you talking about dyspareunia?

A. No. I'm talking specifically perioperative incisional pain.

Q. Do you have an opinion within a reasonable degree of medical certainty whether or not TVT, when compared to pubovaginal slings or Burch slings, causes more dyspareunia or vaginal pain on a long-term basis?

MR. SNELL: Objection. Beyond the scope. Non-disclosed opinion in the report.

Go ahead.

A. Based upon my clinical experience, my discussion with colleagues, review of the literature, and what is outlined in my expert report, TVT, in the long-term, causes increased risk for dyspareunia and the severity of that dyspareunia.

Q BY MR. CARTMELL: What about with vaginal pain?

A. Vaginal pain would be the --

MR. SNELL: Same objection. Go ahead.

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Doctor. I'm sorry.
A. They would be the same. Vaginal pain implies a constant vaginal pain. Dyspareunia is just during sexual activity. And, yes, in my experience, I do not see pubovaginals and Burchs come in with that type of pain. On a daily basis, I see the TVT that way.
MR. CARTMELL: Okay. That's all I have.
MR. SNELL: A couple of quick questions in follow-up.
EXAMINATION
BY MR. SNELL:
Q. Cobb, Klosterhalfen and Klinge, none of those are pelvic surgeons; correct?
A. Clave, I don't know what he is. The first two, Klinge and Klosterhalfen are pathologists, I believe.
Q. Cobb is not --
A. Cobb is not. And I don't know if I mentioned it. I mentioned -- Clave should be on there, and I believe he is a pelvic surgeon, but I don't know his specific credentials.
Q. But Cobb, Klosterhalfen, Klinge, none of them published on the TVT device assessed in

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women; correct?
A. That is correct, yes.
Q. Just so we're clear on the record, the increased perioperative incisional pain that you just talked to Mr. Cartmell about, that actually occurs in the autologous pubovaginal arm; is that correct?
A. That is correct. It would be fair to say that, in my experience, the immediate perioperative period, you will have an increased incisional pain that is still treated with medications and tolerable, but it will be more than the TVT.
Q. Now, I believe you said that you believe that the long-term dyspareunia rates with the TVT were higher than pubovaginal, did you say, and the Burch?
A. I don't recall if I mentioned the Burch in there.
What I mentioned was the pubovaginal and the Burch have traditionally been a very common procedure done up until the mid-'90s and into probably early 2000's.
And in my practice, I have never seen a woman come in with severe pain, life altering

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pain from either of those aforementioned procedures. But I see it commonly, weekly with the meshes, including the TVT.
Q. You can't point to any comparative trials that show a statistically significantly higher rate of dyspareunia for the TVT retropubic device compared to either the Burch or the pubovaginal sling; correct?
A. Those studies, as you've mentioned, have not been done.
Q. And actually, the one paper you pointed me to earlier about the Burch had the 4 percent rate of dyspareunia with that procedure long-term; correct?
A. It wasn't 4 percent. It was 3.9 percent.
Q. So -- okay. If you round up, it's 4 percent; correct?
A. I don't round up, though.
Q. Okay. And you can't point to any studies on TVT that show a rate higher than 3.9 percent at that length of follow-up for dyspareunia; can you?
MR. CARTMELL: Object to the form.
A. Because that study has not been done.

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As I mentioned, no studies focused specifically on output -- end point of dyspareunia have been done.
Q BY MR. CARTMELL: So the answer to my question is, yes, you can't point to that study; correct?
MR. CARTMELL: Object to the form. Asked and answered.
A. That's what I mentioned. Those studies with that specific end point have not been done.
Q BY MR. CARTMELL: Except you know that there's a 10-year TVT retropubic study, lead author Heinonen, that reports zero cases of dyspareunia at 10 years follow-up.
Did you know that?
A. You would have to show me that study.
Q. Do you know that study?
A. I'm saying, you'd have to show me that study. I've read a lot of studies. I can't recall that one specifically. So I'd have to look at that.
Q. So you very well may be wrong when you make statements like there's no long-term studies that look at TVT and dyspareunia?
MR. CARTMELL: Object to the form.

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Q. BY MR. SNELL: Correct?
A. Also certain studies I've looked at, I disregard --
Q. Can you say yes or no?
MR. CARTMELL: Let him answer the question?
A. That's not a yes or no. It's more complicated than that. I review a lot of studies. Some of them get disregarded because they're so poor quality that they're not worth quoting. So that particular study I'd like to see and we can dissect that one out.
Q. And if I'm correct --
MR. CARTMELL: You said a couple. So you went over 7 hours. And I'm here for the MDL portion.
MR. SNELL: I didn't go over 7 hours.
MR. CARTMELL: You went 7 hours and 13 minutes.
MR. SNELL: No, no. That was 6 hours; wasn't it?
MR. CARTMELL: No. It was 7 hours and 13 minutes. I let you ask a few. We done.
MR. SNELL: Okay.
MR. CARTMELL: And you could have

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saved your time.
MR. SNELL: Well, I have two more considering you've asked him to comment and say rates are higher. That's not even in his expert report, okay. He doesn't put in his expert report what the rates are for Burch, for the pubovaginal, or the TVT.
MR. CARTMELL: I didn't ask him what the rates were.
MR. SNELL: Yes, you did.
MR. CARTMELL: No, I didn't. I said --
MR. SNELL: You said higher.
MR. CARTMELL: -- the claim is it's higher, and it says that in his expert report.
MR. SNELL: No, it doesn't.
MR. CARTMELL: Yes, it does.
MR. SNELL: It can't be higher. He doesn't even have the rates.
Q BY MR. SNELL: How about this? You've seen the AUA guideline from 2012 and the SGS systematic meta-analysis and review, and in both of those systematic reviews, they report higher rates of dyspareunia, pain, and sexual dysfunction with the autologous sling and the Burch as

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compared to the mid-urethral sling; correct?
A. I'd have to look at that. That's a 799-page document. I'd have to see that.
Q. As you sit here today, you can't answer my question?
A. Oh, I can answer. Let's pull out the document, take a look at it.
Q BY MR. SNELL: Do you want to do that?
MR. CARTMELL: I mean, I'm not giving you any more time. So you don't have the time to do that. This whole day you've been asking him questions about things and you've been making statements from those documents without showing them to him.
MR. SNELL: No, no. He's got these documents.
MR. CARTMELL: No, no.
MR. SNELL: I wouldn't misrepresent.
MR. CARTMELL: All day long.
MR. SNELL: Do you want me to show him the numbers? You know the numbers. I used them with Dr. Rosenswath.
MR. CARTMELL: No. I want to be done. You're over your 7 hours. So let's go.
Q BY MR. SNELL: As you sit here,

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Doctor, can you answer my question without me showing you those papers?
A. I want to see those papers.
MR. CARTMELL: No.
MR. SNELL: Fair enough.
MR. CARTMELL: The question was: Can you answer it without seeing the papers. If you can't answer it without seeing it, just say no.
A. I cannot answer it without it. It's a 799-page document. I would need to see those papers.
MR. SNELL: Fair enough.
MR. CARTMELL: Go ahead. Thank you very much.
(Deposition concluded at 5:54 p.m.)

REPORTER'S CERTIFICATE

I, NAOLA C. VAUGHN, a Certified Court Reporter within and for the States of Missouri and Kansas, hereby certify that the within-named witness was first duly sworn by me to testify to the truth; and that the deposition by said witness was given in response to the questions propounded, as herein set forth; was first taken in machine shorthand by me and afterwards reduced to writing under my direction and supervision; and is a true and correct record of the testimony given by the witness.

I further certify that I am not a relative or employee or attorney or counsel of any of the parties, or a relative or employee of such attorneys or counsel, or financially interested in the action.

WITNESS my hand and official seal at Tonganoxie, Kansas, this 29th day of September 2015.

____

NAOLA C. VAUGHN, CCR, CRR, RPR
Missouri CCR No. 1052
Kansas CCR No. 0895

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ACKNOWLEDGMENT OF DEPONENT

I,____________________, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

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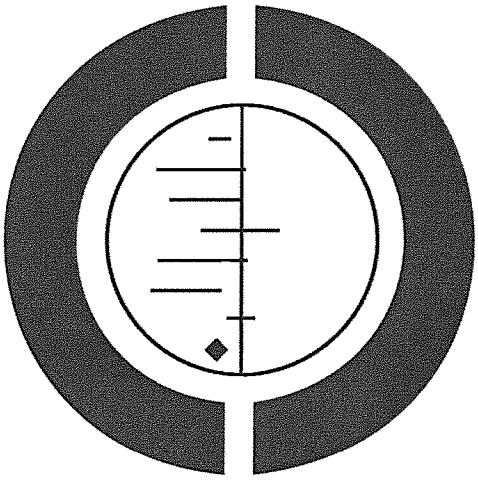
Ford AA, Rogerson L, Cody JD, Ogah J



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Mid-urethral sling operations for stress urinary incontinence in women (Review)
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EXHIBIT # 4
D. ELLIOTT. M.D.
9/26/15 ncv

[Intervention Review]

Mid-urethral sling operations for stress urinary incontinence in women

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ABSTRACT

Background

Urinary incontinence is a very common and debilitating problem affecting about 50% of women at some point in their lives. Stress urinary incontinence (SUI) is a contributory or predominant cause in 30% to 80% of these women. Mid-urethral sling (MUS) operations are a recognised minimally invasive surgical treatment for SUI. MUS involves the passage of a small strip of tape through either the retropubic or obturator space, with entry or exit points at the lower abdomen or groin, respectively. This review does not include single incision slings.

Objectives

To assess the clinical effects of mid-urethral sling (MUS) operations for the treatment of stress urinary incontinence (SUI), urodynamic stress incontinence (USI) or mixed urinary incontinence (MUI) in women.

Search methods

We searched the Cochrane Incontinence Group Specialised Register, which contains trials identified from CENTRAL, MEDLINE, MEDLINE in process, ClinicalTrials.gov and handsearching of journals and conference proceedings (searched 26 June 2014), Embase and Embase Classic (January 1947 to Week 25 2014), WHO ICTRP (searched on 30 June 2014) and the reference lists of relevant articles.

Selection criteria

Randomised or quasi-randomised controlled trials amongst women with SUI, USI or MUI, in which both trial arms involve a MUS operation.

Data collection and analysis

Two review authors independently assessed the methodological quality of potentially eligible studies and extracted data from the included trials.

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Main results

We included 81 trials that evaluated 12,113 women. We assessed the quality of evidence for outcomes using the GRADE assessment tool; the quality of most outcomes was moderate, mainly due to risk of bias or imprecision.

Fifty-five trials with data contributed by 8652 women compared the use of the transobturator route (TOR) and retropubic route (RPR). There is moderate quality evidence that in the short term (up to one year) the rate of subjective cure of TOR and RPR are similar (RR 0.98, 95% CI 0.96 to 1.00; 36 trials, 5514 women; moderate quality evidence) ranging from 62% to 98% in the TOR group, and from 71% to 97% in the RPR group. Short-term objective cure was similar in the TOR and RPR groups (RR 0.98, 95% CI 0.96 to 1.00; 40 trials, 6145 women). Fewer trials reported medium-term (one to five years) and longer-term (over five years) data, but subjective cure was similar between the groups (RR 0.97, 95% CI 0.87 to 1.09; 5 trials, 683 women; low quality evidence; and RR 0.95, 95% CI 0.80 to 1.12; 4 trials, 714 women; moderate quality evidence, respectively). In the long term, subjective cure rates ranged from 43% to 92% in the TOR group, and from 51% to 88% in the RPR group.

MUS procedures performed using the RPR had higher morbidity when compared to TOR, though the overall rate of adverse events remained low. The rate of bladder perforation was lower after TOR (0.6% versus 4.5%; RR 0.13, 95% CI 0.08 to 0.20; 40 trials, 6372 women; moderate quality evidence). Major vascular/visceral injury, mean operating time, operative blood loss and length of hospital stay were lower with TOR.

Postoperative voiding dysfunction was less frequent following TOR (RR 0.53, 95% CI 0.43 to 0.65; 37 trials, 6200 women; moderate quality evidence). Overall rates of groin pain were higher in the TOR group (6.4% versus 1.3%; RR 4.12, 95% CI 2.71 to 6.27; 18 trials, 3221 women; moderate quality evidence) whereas suprapubic pain was lower in the TOR group (0.8% versus 2.9%; RR 0.29, 95% CI 0.11 to 0.78); both being of short duration. The overall rate of vaginal tape erosion/exposure/extrusion was low in both groups: 24/1000 instances with TOR compared with 21/1000 for RPR (RR 1.13, 95% CI 0.78 to 1.65; 31 trials, 4743 women; moderate quality evidence). There were only limited data to inform the need for repeat incontinence surgery in the long term, but it was more likely in the TOR group than in the RPR group (RR 8.79, 95% CI 3.36 to 23.00; 4 trials, 695 women; low quality evidence).

A retropubic bottom-to-top route was more effective than top-to-bottom route for subjective cure (RR 1.10, 95% CI 1.01 to 1.19; 3 trials, 477 women; moderate quality evidence). It incurred significantly less voiding dysfunction, and led to fewer bladder perforations and vaginal tape erosions.

Short-and medium-term subjective cure rates between transobturator tapes passed using a medial-to-lateral as opposed to a lateral-to-medial approach were similar (RR 1.00, 95% CI 0.96 to 1.06; 6 trials, 759 women; moderate quality evidence, and RR 1.06, 95% CI 0.91 to 1.23; 2 trials, 235 women; moderate quality evidence). There was moderate quality evidence that voiding dysfunction was more frequent in the medial-to-lateral group (RR 1.74, 95% CI 1.06 to 2.88; 8 trials, 1121 women; moderate quality evidence), but vaginal perforation was less frequent in the medial-to-lateral route (RR 0.25, 95% CI 0.12 to 0.53; 3 trials, 541 women). Due to the very low quality of the evidence, it is unclear whether the lower rates of vaginal epithelial perforation affected vaginal tape erosion (RR 0.42, 95% CI 0.16 to 1.09; 7 trials, 1087 women; very low quality evidence).

Authors' conclusions

Mid-urethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence (SUI) in women and have a good safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long term. This review illustrates their positive impact on improving the quality of life of women with SUI. With the exception of groin pain, fewer adverse events occur with employment of a transobturator approach. When comparing transobturator techniques of a medial-to-lateral versus a lateral-to-medial insertion, there is no evidence to support the use of one approach over the other. However, a bottom-to-top route was more effective than top-to-bottom route for retropubic tapes.

A salient point illustrated throughout this review is the need for reporting of longer-term outcome data from the numerous existing trials. This would substantially increase the evidence base and provide clarification regarding uncertainties about long-term effectiveness and adverse event profile.

PLAIN LANGUAGE SUMMARY

Mid-urethral sling operations for stress urinary incontinence in women

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Background information

Stress urinary incontinence (involuntary leakage of urine on effort or exertion; or on sneezing, coughing or laughing) is the commonest form of incontinence in women and leads to a reduction in their quality of life. Women with stress urinary incontinence can also have problems with sexual intercourse, as leakage of urine can occur. One in three women over the age of 18 years will be affected by stress urinary incontinence at some point in her lifetime.

Over the years, surgery to stop this problem has become less invasive, and there are many different types of operations available. Mid-urethral sling operations are commonly undertaken to try and cure stress urinary incontinence. These operations are suitable for women who are having their first operation to prevent incontinence, and also women who have had unsuccessful surgery previously. In a mid-urethral sling operation a tape is placed underneath the urethra, which is the tube that carries urine out of the bladder. When the woman coughs, the tape compresses the tube, thus providing the support necessary to prevent urine leakage.

There are two main ways of carrying out these operations, either by inserting a tape behind the pubic bone through the abdomen ('retropubic'), or through the groin ('transobturator').

What this review tried to find out

We looked at the effects of mid-urethral sling operations when these two different methods of performing the operations were used. We also compared different ways of inserting the tape, and using tapes made from different materials. The purpose of this review was to find out how effective these operations are in the treatment of stress urinary incontinence and to help determine the rate of potential complications or problems.

Main findings of this review

We performed a thorough search of the medical literature up to June 2014. We identified 81 trials that had a total of 12,113 women. These trials showed that over 80% of women with stress urinary incontinence are cured, or have significant improvement in their symptoms, with either operation, for up to five years after surgery. We found this to be the case irrespective of the tapes used and the route of tape insertion. The studies used different questionnaires to assess quality of life, which meant that we could not combine their results for analysis. However, the information that is available for quality of life shows that it improves as a result of these operations, though there is no clear difference between the two procedures. Only a few trials provided information about the effectiveness of these tapes more than five years after surgery. The evidence that we have been able to assess indicates that the positive effects persist.

Adverse effects

Tapes passing behind the pubic bone (retropubic) seem to carry a greater risk of injuring the bladder during the operation and of women experiencing problems emptying their bladder completely after surgery. However, this operation leads to less groin pain in the short term. There is some limited evidence that this way of inserting the tape has a lower risk of requiring a repeat operation in the long term compared to tapes passing through the groin (transobturator). There is moderate quality evidence that overall reported rates of tape-related complications are low, such as erosion of the tape into the vagina at about 2% for both routes of tape insertion. The reported occurrence of problems with sexual intercourse including pain was low, and leakage of urine during intercourse are improved following insertion of these tapes.

Limitations of the review

Most of our results are based on moderate quality evidence. Most trials did not describe their methods clearly, thus leading to some degree of uncertainty in the findings. At present there are only a limited number of randomised controlled trials (these produce the most reliable results) that have published data beyond five years after surgery. This means that evidence about how effective and safe these procedures are in the longer term lags behind the evidence for them in the short and medium term (up to five years). We encourage researchers to publish longer-term data to help increase the reliability of longer-term results in this area.

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